

Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering

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Final Report

of the Expert Group on the development and
implications of patent law in the field of biotechnology and
genetic engineering

(E02973)

17 May 2016

**Directorate General Internal Market, Industry,
Entrepreneurship and SMEs
(DG GROW)**

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Foreword

It is with pleasure that I present to you the Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering. This Final Report consists of the three Subreports which have been drafted by the respective Rapporteurs¹ relating to the respective widely defined topics (on which more further below) which have been discussed during the work of the Group and which present the results of the discussions and the findings of the Expert Group on the topics discussed. Each Subreport discusses one of the widely defined topics.

By Commission Decision of 7 November 2012² this Commission Expert Group was set up. According to the Decision, the task of the Expert Group was “to provide the Commission with the necessary legal and technical expertise regarding intellectual property law practice and intellectual property law administration, public and industrial research and development, life sciences including plant and animal breeding, and biotechnology in the context of the application of Directive 98/44/EC, with the exception of ethical issues related to that Directive, which are the mandate of the European Group on Ethics in Science and New Technologies”. The task of the group of Experts was further “to assist and advise the Commission in its reporting requirements under Article 16, paragraph (c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions” (hereinafter referred to as 'Biotech Directive').

The Expert Group consisted of 15 members. Some members had been appointed in their personal capacity, others had been appointed as representatives of certain interests.³

The Group met in total 18 times in person in Brussels. Additionally, there were frequent exchanges of views and opinions via e-mail between the members.

The first meeting was held on 12 December 2013, during which the Expert Group members were introduced, the scope of the mandate of the Group was discussed and further procedural issues were dealt with. During the second and third meeting, a Chairman was appointed and further procedural issues were discussed. At the initiative of the Chair, it was decided to work with sub-groups covering each a separate widely defined topic, and for each sub-group a rapporteur was appointed who was responsible for drafting a report for that specific largely defined topic. Those reports have now led to the aforementioned Subreports.

The Expert Group took ample time to discuss and evaluate which topics were of particular interest to be discussed. To that effect, a so-called “mapping exercise” was held, and the Group discussed a variety of possible topics during meetings 2-4.

The Group agreed that two topics deserved immediate discussion, i.e.

- 1) the (non-)patentability of human embryonic stem cells and the related use of human embryo's for industrial or commercial purposes; and

¹ Names of the Rapporteurs can be found further below when each individual Subreport is being discussed.

² COMMISSION DECISION of 7.11.2012 on setting up a Commission Expert Group on development and implications of patent law in the field of biotechnology and genetic engineering, C(2012) 7686 final.

³ For further details on the composition of the Group, see Register of Commission Expert Groups, <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2973> (last visited 2 May 2016).

- 2) (non-)patentability of plant related inventions, with particular emphasis on essentially biological processes for the production of plants and the plant obtained by such processes and the breeders' exemption.

As agreed in previous meetings, a sub-group was set up for each of the abovementioned widely defined topics and a Rapporteur was appointed responsible for the drafting of a report.

As per the agreed Working Methods, discussions on the topics took place predominantly in the sub-groups, with a reporting session to the plenary at the end of each meeting.

A considerable number of meetings were spent on the discussions in the sub-groups and the drafting of the reports for each topic. The discussions were very thorough, fruitful and at times quite animated indeed. The discussions lasted for somewhat more than a year.

A number of further meetings were subsequently spent on the plenary discussions of the reports on both aforementioned topics with a view to come to the now final Subreports.

In parallel to the plenary discussion of the Subreports, the "mapping exercise" was resumed and new potentially relevant topics were discussed. The Group agreed that the topic of "scope of protection of nucleic acid related inventions" deserved specific attention, also in light of the Monsanto judgement by the Court of Justice of the European Union (C-428/08) of 6 July 2010. This topic was subsequently discussed in detail, and in plenary only, during all of the remaining meetings.

The Group has tried to achieve consensus on all of the aforementioned topics. This has, however, shown not possible, as the views were at times too far apart. It has therefore been decided that the Group would work with majority and minority views, and Group members were furthermore given the opportunity to submit Dissenting Opinions to the Subreports, which has indeed happened at a number of occasions. This Final Report makes reference to and contains those Dissenting Opinions to each of the Subreports.

In terms of conclusions drawn by the Expert Group, it deserves to be emphasised that across all topics discussed, which can also be seen in the Subreports, the overwhelming majority of Experts were not in favour of reopening the Biotech Directive. The Subreports show a more detailed discussion, but it is worth noting that, even though the Expert Group identified several issues which may not necessarily have been resolved entirely and faultlessly satisfactory by the Biotech Directive and/or by case law interpreting the Biotech Directive, a very solid large majority did not see any positive prospect in reopening the Biotech Directive with a view to resolve some or all of these issues. One of the considerations of that majority was that reopening the Biotech Directive would be tantamount to opening "Pandora's Box", and the Experts doubted whether it would be in the interest of research, industry and society as a whole to plunge oneself into a new and very likely long negotiation process to review and amend the Biotech Directive.

In terms of each of the Subreports covering each one of the abovementioned widely defined topics, the following can be said.

Plant related inventions

In respect of the topic of plant related inventions,⁴ the Expert Group discussed the following issues, more details on which can be found in the respective Subreport pertaining to that topic. This Subreport starts with an overview of recent technological developments in the area, which was seen as indispensable for a good understanding of the patentability questions. In a second chapter, the Subreport discusses the issues relating to the non-patentability of essentially biological processes for the production of plants. Particular attention was dedicated to the case law of the Enlarged Board of Appeal (EBA) of the European Patent Office (G 2/07) which ruled that the equivalent provision of Article 2(2) of the Biotech Directive was internally inconsistent and contradictory, and an autonomous interpretation had to be given to the concept of “essentially biological process”, which the EBA has done in the aforementioned decision. The Subreport contains a detailed discussion of the findings of the Group in this regard.

A subsequent issue was then the question of whether plants obtained by essentially biological processes are excluded from patentability. In the absence of a specific treaty provision to that effect, either in the European Patent Convention or in the Implementing Rules, the EBA concluded in G 2/12 and G 2/13 that this is not the case, and that such plants are patentable. The Subreport provides a detailed reasoning as to what the Group’s thoughts are on this particular issue.

A third topic of discussion related to the dichotomy between the patentability of plants and the non-patentability of plant varieties. The Subreport provides detailed insight into the various views on this issue and presents the findings of the Group.

In a fourth subject, the Group discussed at length the so-called breeders’ exemption. The conclusions of the Group as to the positive and negative effects of introducing such exemption can be found in this Subreport.

As a final issue, compulsory cross-licensing as laid down in Article 12 of the Biotech Directive was discussed, and the Subreport contains the conclusions of the Group.

This Subreport relating to plants shows quite a large diversity of opinions between the Experts. This Subreport therefore presents the opinion of the majority of the Experts. However for the sake of completeness and of full transparency, dissenting opinions on specific items are enclosed to that Subreport.

Patentability of human stem cells

This Subreport relating to human stem cells⁵ starts with a discussion of the relevant technology. The Group had the benefit of having invited Professor Peter Andrews, Professor of Biomedical Science at the University of Sheffield and a world authority in this particular area of science.

⁴ See p6 - The Rapporteur for this Report was Mr. Hannes Iserentant.

⁵ See p 127 - The Rapporteur for this Report was Ms. Clara Sattler de Sousa e Brito.

Not surprisingly, both the *Brüstle v. Greenpeace* (C-34/10) and the *International Stem Cell Cooperation Corporation vs. Comptroller General* (C-364/13) judgements by the CJEU took centre stage in the discussions and the Report.

The discussions and the Subreport focussed on a number of identified issues:

- 1) Meaning of the term “human embryo”, which has also been covered by the aforementioned CJEU judgements;
- 2) Meaning of the term “use”, which contained in fact three distinctive hypothetical situations, i.e. a) A process or substance which itself requires the use of a human embryo; b) A process or substance which depends on a prior, “upstream,” destruction of a human embryo; and c) A process or substance which depends on a prior, “upstream” non-destructive use of a human embryo.

The Subreport contains a detailed overview of the discussions held and the conclusions reached in this regard.

As can be seen in the Subreport, even though most conclusions drawn gained support from an overwhelming majority of Experts, consensus could also not be reached here. Therefore, the same approach as for the plant-related issues was applied to this Subreport, i.e. a main report followed by dissenting opinion on selected issues.

Scope of protection of nucleic acid related inventions

This Subreport regarding the scope of protection of nucleic acid related inventions⁶ generally relates to the breadth of the scope of protection afforded by a patent claim to a nucleic acid molecule and in particular to the concept of “absolute product protection” for a nucleic acid molecule, where a patentee is awarded protection for a nucleic acid molecule per se, regardless of the manner in which the nucleic acid molecule was obtained and irrespective of the any intended use of the nucleic acid molecule.

The Subreport first summarizes the historical development of absolute product protection in Europe. It subsequently provides relevant passages of Directive 98/44/EC and the transposition of the Directive into national law and into the European Patent Convention. It finally examines recent developments in European patent case law stemming from the Court of Justice of the European Union (CJEU) in decision C-428/08 relating to the scope of protection conferred by a patent claim directed to DNA, and in particular to isolated genomic DNA, i.e. the genetic material of living beings, as well as the implications of these developments.

A large part of this Subreport is dedicated to identifying the exact meaning and scope of the judgement of the CJEU in the *Monsanto* case. Building on the detailed discussion regarding the possible interpretations and resulting implications of the Biotech Directive in so far as it relates to product protection of nucleic acids which was already carried out in a previous Report⁷ annexed to

⁶ See p 176 - The Rapporteur for this Report was Mr. Joseph Taormino.

⁷ S.J.R., Bostyn ‘Patenting DNA Sequences (Polynucleotides) and Scope of Protection in the European Union: An Evaluation’, Luxemburg, European Communities 2004, +146 pp. (ISBN 92-894-7674-5).

the 2005 Commission's report on the development and implications of patent law in the field of biotechnology and genetic engineering, which was published prior to CJEU decision C-428/08, the Subreport draws certain conclusions.

Also on this particular issue, the Expert Group could not reach consensus. An overview of arguments which discuss in a critical manner the claimed advantages of absolute product protection can be found in Annex 5 to that particular Subreport, whilst an overview of arguments in favour of purpose- or function-limited product protection can be found in Annex 6 to that particular Subreport.

I would like to take the opportunity to thank all colleagues in the Expert Group for their dedication and their limitless efforts in contributing to the discussions on issues which are of crucial importance to society as a whole. I have enjoyed their presence and have been impressed by the quality of their thinking. Special thanks also to the Rapporteurs who have done a fantastic job in drafting the respective Subreports.

Allow me finally to express my sincere gratitude and respect to the people of the European Commission's services, who have worked extremely hard during this more than 2 year period to act as the Secretariat to the Expert Group and provide all the support conceivable to the activities of the Expert Group.

I hope that this Final Report will provide interesting reading and a useful tool for future action and thinking.

Brussels, 13 May 2016

Dr. Sven J.R. Bostyn

Chair Expert Group

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A. Subreport on Plant related Inventions

Executive summary

The question which needs to be answered is whether technological developments in the last decade should lead the Commission to rethink the statutory and policy regime vis-à-vis plant related inventions.

Several issues have been identified (the scope of essentially biological processes, the patentability of products obtained by essentially biological processes, the interface between patents for plant-related inventions and plant variety protection, the breeders' exemption, and compulsory cross-licensing). These issues are discussed in detail in separate chapters.

Each chapter presented herein concludes with recommended actions the Expert Group suggests to the Commission. In this context the Expert Group always considered the following possible actions which are evaluated in each chapter.

- 1) A recommendation that no action nor clarification is needed (either because the situation is not problematic, or because case law can better resolve potential issues than other actions would, or because there are concerns that an amendment of the Biotech Directive entails too many risks);
- 2) A recommendation for clarification of the meaning of the provisions of the directive. This could be done through a communication/guidelines or interpretation of the Directive by the Commission (without legislative action);
- 3) A recommendation for legislative action. A distinction is made between recommendations for separate legislation (which excludes amendment of the Biotech Directive), and recommendations for legislation by clarification or amendment of the present legal text of the Biotech Directive.

Of note, for all issues under consideration, there was no Expert who recommended the option of amending the text of the Biotech Directive as a first option. Rather, those Experts who saw this recommendation as a possible solution for the respective issues preferred a stepwise approach, i.e. amendment of the Biotech Directive is only envisaged if a clarification or legislation outside of the Biotech Directive is not feasible or sufficient.

The (conclusions in the) chapters themselves provide more background on the reasons for the recommendations, and the exact nature of the proposed action. Where possible, unanimity was sought. If this was not possible, then a consensus view supported by the largest possible majority is presented, as well as the minority opinions.

In the Biotech Directive, and the European Patent Convention (EPC), inventions which concern plants are deemed patentable if the technical feasibility of the invention is not limited to a variety. For plant varieties, protection can be obtained through Plant Variety Right (PVR).

When discussing plant-related patents, the discussion often centres on plants obtained by genetic engineering. Indeed, the number of patents on plant-related inventions increased when this technology became available. It should be kept in mind, however, that the entry into force of the

European patent convention predates the first transgenic plant by 10 years, meaning that the legislator could not have had the intention to limit patentability of plant related inventions to transgenic plants and processes of genetic modification.

Although there is controversy surrounding genetic engineering of plants in the EU, this is predominantly for non-patent related reasons. Rather, public policy arguments have been forwarded to oppose those patents. From a purely patent perspective, both the processes to produce such plants and the resulting plants did not exist before, they contain a clear technical step and thus are less controversial from a patent point of view.

While the EU imports and utilises substantial amounts of genetically modified (GM) maize and soybeans, marketing and cultivation of GM seeds in Europe is very limited – again, mainly due to regulation and public perception issues and not for patent-technical reasons⁸. However, next to GMOs, many alternative technologies incorporating the new knowledge of molecular technology were developed and/or marketed during the last decade (discussed in Chapter 1). These have come centre stage, predominantly but not necessarily exclusively because of the fact these technologies have entered the area of breeding (more background of this field is provided in Chapter 1). As some of these technologies combine new molecular insights with traditional breeding practices, the question arose as to whether these technologies are patentable, or whether they relate to essentially biological processes.

As discussed in Chapter 2, finding an exhaustive definition of “essentially biological process” is probably an impossible task indeed, and maybe not even worth trying. Experience from other areas of technology, such as software related inventions, shows that the search for an all embracing definition often implies decades of legal uncertainty without any outcome. It is doubtful whether more – and more prolonged – legal uncertainty is desirable in the field of plants. The Expert Group has come to the conclusion that a minimum definition of essentially biological process for the production of plants should at least contain the elements laid out in G2/07 (crossing of whole genomes), but considers that this definition does not necessarily cover all essentially biological processes, nor does it mean that a process is already “essentially biological” only because it includes a step of sexual crossing. It is rather the technical character and essentiality of the other technical steps which needs to be given stronger consideration.

In respect of the products obtained by essentially biological processes, this topic has been addressed by two decisions of the Enlarged Board of Appeal of the European Patent Office (EPO), G2/12 and G2/13, which rule that these products are patentable. The decisions and their consequences are briefly addressed in Chapter 3. It must be said, however, that these decisions as such do not resolve the issue under EU law, which would require a decision by the Court of Justice of the EU (CJEU) on this issue. However, legal certainty is not affected by this decision, because all EU countries are members of the EPC. In addition, the Expert Group is not aware of any national court decision (either

⁸ One patent-technical issue is addressed in G1/98, which dealt with the question whether a patent to a (transgenic) plant covers plant varieties and makes as such the exclusion of plant varieties from patent protection obsolete.

in non-EU EPC countries or in EU countries) for national patents contradicting the respective decisions of the Enlarged Board of Appeal⁹.

Given that inventions relating to plants can be protected by patents and plant varieties by plant variety rights, there is a clear interface between these two systems. The repercussions of this interface, and whether recent developments mark a paradigm shift, are discussed in Chapter 4. While the majority of the Experts agreed that the situation has not really changed, some Experts argued that at least clarifications are needed to better distinguish between patents concerning plants and plant variety rights, particularly with regard to plants obtained by essentially biological processes.

With regard to the limited breeders' exemption under patent law (Chapter 5), it was concluded that there are arguments in favour of and against the introduction of such an exemption, but the majority vote is that no action is necessary. Two thirds of this majority is even explicitly against such an exemption, but since it has now been introduced into the Unified Patent Court Agreement (UPC Agreement), it is probably a given fact. Despite this UPC provision, a significant minority of Experts argues for additional separate legislation, as not all EU Member States are party to the UPC.

The compulsory cross licensing provisions (chapter 6) in the Biotech Directive are not very practicable, and are difficult to interpret, but as the concept is not used, and also in view of the fact that the uncertainties created by the wording of the provisions are not different from already long-standing compulsory licensing provisions (e.g. in the Member States and under TRIPs), there is no need for the Commission to undertake any action.

Effective licensing — bilaterally or via a multilateral system — as applied for certain crops, can provide the opportunity for access to patented subject matter by mutual agreement of terms. With regard to multilateral licensing systems, an example is the International Licensing Platform (ILP) for plant breeding innovations in vegetables that was launched at the end of 2014 (see chapter 6).

Please note that there are dissenting opinions attached to this report on particular topics. References to these dissenting opinions have been inserted in the relevant sections of the report.

⁹ National court decisions C/09/416501/HA ZA 12-452 and C/09/418860/HA ZA 12-577 of 8 May 2013 are in fact in line with the Enlarged Board of Appeal decisions.

Chapter 1. Introduction on plant breeding and recent technological developments

1.1 Background on plant breeding

Plant breeding is the science of adapting the genetics of plants for the benefit of society. The overall aim of plant breeding is to improve the quality, diversity and performance of crops with the objective of developing plants better adapted to human needs.

As the understanding of nature and its processes developed, plant breeding activities suddenly became much more advanced. Modern chemistry, biology, genetics and also information technology have enhanced the possibilities of plant breeders who brought their new understanding of genetics to the traditional techniques of self-pollinating and cross-pollinating plants. Nowadays many different breeding techniques, ranging from simple selection to more complex molecular technologies, are used to develop plants exhibiting desired characteristics¹⁰.

Notwithstanding all these developments, plant breeding remains largely based on crossing and selection; a sophisticated, time consuming and high-investment business with long-term goals. The average R&D investment of the plant breeding sector is between 4-20% of its annual turnover, depending on the specific crop¹¹.

The development of one single new variety is a complicated process and can easily take up to 12 to 15 years. The breeding process starts with the selection of genetic resources presenting the desired characteristics which are then crossed and recombined. Then, from the mixed lines and breeding material so developed, the best plants are selected and stabilized, which can take up a number of years. The newly developed variety then needs to be tested in different climates and conditions, which again is a lengthy process. At the end, the new and improved variety presenting added value for the farmer has to be multiplied for distribution. This process is illustrated by the following drawing:

¹⁰ A dissenting opinion is provided (Annex III), see Chapter 7 therein

¹¹ The figures are kindly provided by ESA. See e.g. document ESA_12.0100 ESA Position on Intellectual Property protection for plant-related inventions in Europe, available on <https://www.euroseeds.eu/esa120100-esa-position-intellectual-property-protection-plant-related-inventions-europe>

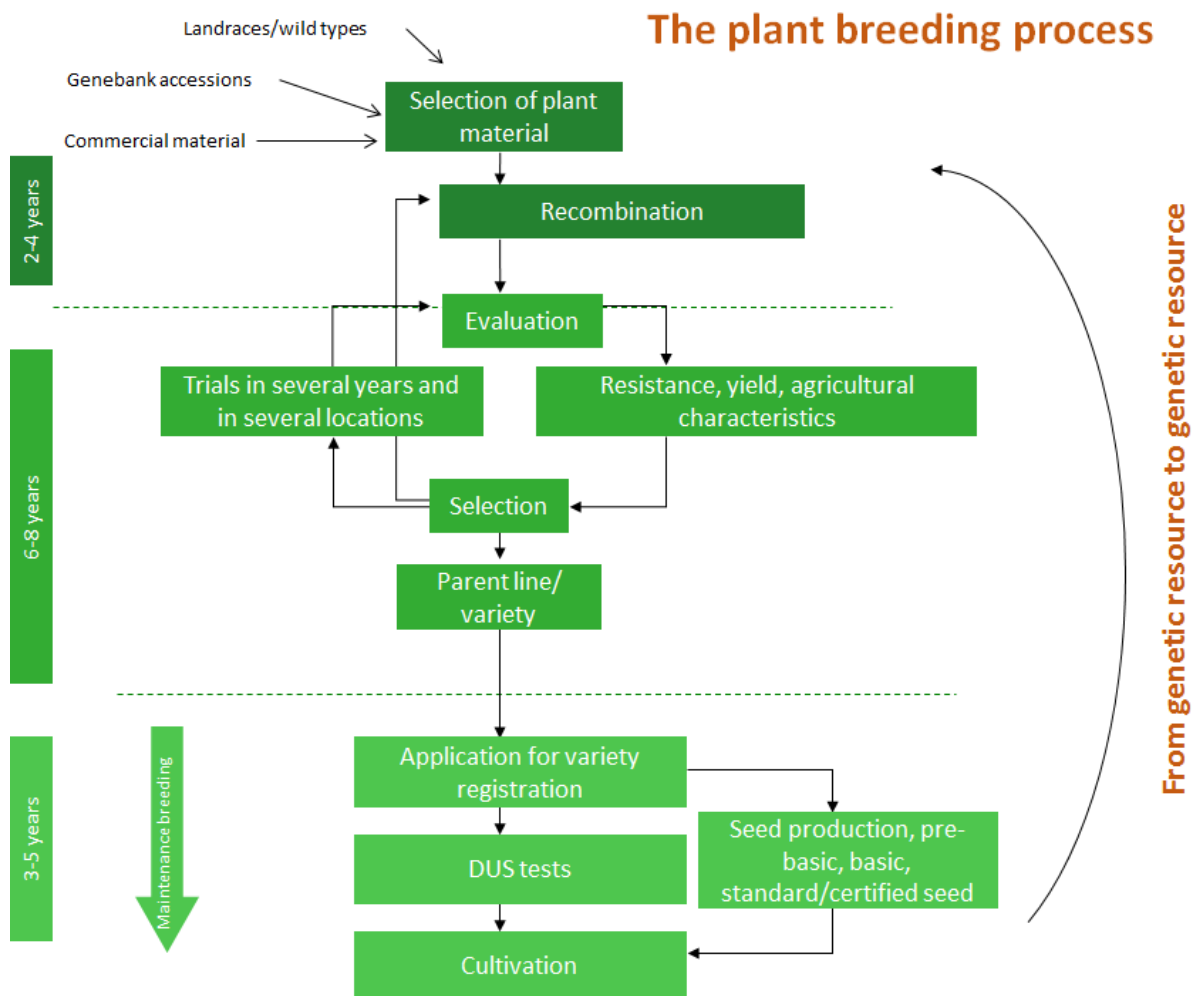


Figure 1.1 A schematic overview of an exemplary plant breeding process. (courtesy of ESA)

The aim of a breeding program is to arrive in the end to one or a few varieties (a commercial product). Nevertheless, in order to be able to deliver on the defined breeding goals, a breeder will want to start with the widest possible diversity, to be able to screen a lot of material to identify the ones which are interesting to cross with, and to create further diversity with the material identified as interesting. This is done through a number of years with the aim of always narrowing the basis from which material is selected for further crosses, since the aim is to arrive in the end to one or a few varieties responding to the breeding goals. This is why full, and preferably full free, access to all plant genetic resources for further breeding is considered as important for plant breeders. Moreover, some plant traits are regarded as “must-have”¹² for all new varieties, so breeders want to have access to these in particular. If access to plant genetic material is not ensured, a negative effect on plant breeding and on the genetic diversity of new plant varieties is feared.

1.2 The European plant breeding and seed sector

Europe’s plant breeding sector is still quite diverse compared to the breeding sector in some other parts of the world. There are around 7 200 European seed companies, however often with very different business models. While some are only active in R&D and breeding, others also have

¹² See footnote 17.

activities in seed production or marketing and the biggest multinationals (coming historically from the pharmaceutical or plant protection business) often also have activities in plant protection products. The differences in business models are also linked to the fact that some companies are only active in a few crops while others might have multi-crop portfolios - a business strategy that works for one crop might not work for another. Of the total estimated value of the EU seed market (€7 billion excluding seed produced for export outside the EU) some 39% comes from small grain cereals; 26% from maize; 14% from seed potatoes; 11% from vegetables; 4% from oil and fibre crops; 3% from sugar beet and 3% from grasses¹³. Consumer or farmer demands for new characteristics might be very different from crop to crop and thus the breeding goals and the kind of traits breeders are looking for in the different segments of plant breeding are varying to a large extent. While in cereals for example yield is the key characteristic to breed for, in many vegetable crops disease resistances are the traits breeders are working for. This is part of the reasons why there are more patents in certain crops than in others.

With regard to the different business models, in the past decades the landscape of breeding and seed companies changed significantly due to the entry on the European market of both European and non-European multinational companies with diverse activities which resulted in a number of mergers and acquisitions.

These companies differ to a large extent from the traditional European breeding companies. The companies belonging to the latter category rely on traditional breeding work where breeders mutually depend on each other and exchange germplasm, which allows for a very open and continuous innovation. Indeed, plant breeders in Europe have been using the UPOV-type plant variety rights (PVR) system for decades (and before the adoption of the UPOV (International Union for the Protection of New Varieties of Plants) Convention, the similar national variety protection systems since the beginning of the 20th century) to protect their innovations, i.e. new plant varieties. Since plant varieties are high-value products requiring lots of investments and years of research and development work but are very easy to reproduce since we talk about self-reproductive material, breeders sought IP protection in order to defend themselves from copying. The UPOV-type PVR system is a *sui generis* IP system which has been specifically conceived to provide IP protection for plant varieties as such taking into account all the specificities of the breeding sector. One such key specificity is access to the existing available gene pool (as outlined in section 1.1). To allow plant breeders to continuously improve on each other's material, the UPOV-system has incorporated a so-called 'breeders' exemption' allowing for the free use of protected varieties for further breeding and for the commercialization of the newly bred variety. Companies which already had strong positions e.g. in the pharmaceutical or plant protection sectors and which entered the breeding business more recently typically have business models largely based on patent rights. At the same time an increased concentration among seed companies occurred¹⁴.

¹³ Figures (dating from 2014) kindly provided by ESA, and accessible at https://www.euroseeds.eu/system/files/publications/files/esa_12.0485.7.pdf (last accessed 17 October 2015)

¹⁴ The trend is well described and illustrated in the 2009 study of Wageningen University entitled "Breeding Business, The future of plant breeding in the light of developments in patents and plant breeders' rights", CGN Report 14, Wageningen 2009

As to plant breeding itself, it also has to be noted – as already mentioned above – that due to modern technology and continuous development, new tools have appeared some decades ago allowing for a number of improvements. Most importantly, due to molecular tools breeders are now able to conduct part of their work in the laboratory that reduces (by 2-3 years) the development time of a variety. While to a very large extent breeding is still based on classical crossing and selection work, the emergence of these new tools and methods contributed to the increasing use of patents in the breeding world. The PVR system allows for the protection of plant varieties as such but not of other innovations, such as tools used in breeding, for which the patent system offers protection possibilities. In the 1980s, the first applications were being filed and granted on genetically modified plants and genetic modification techniques and tools. Rapid technical development enabled the manipulation of conventional plants by genetic engineering techniques such as the use of molecular markers. Patents on such techniques and on processes conducted with them as well as on plants bred via such processes appeared.¹⁵

1.3 Practical aspects of the interface between PVR and the patent system

Plant varieties as such and essentially biological processes for the production of plants are excluded from patentability. These exceptions were originally introduced because plant varieties were to be protected by the *sui generis* system of plant variety rights under UPOV. The legislator intended to exclude plant varieties and the conventional breeding methods used at the time from patentability (G2/07, reasons 6.4.2.3). However, in practice – due to the specific nature of plant-related patents and some provisions of patent law and patent practice (see in particular Article 64 EPC; Article 4(2) and Articles 8 and 9 of the biotech directive) – plant varieties nevertheless often fall under the scope of patents. Given that patent laws, in general, do not contain a breeders' exemption (see more in Chapter 5) breeders have to ask patent holders for a licence if they wish to use patented material for further breeding. If no licence can be obtained, this blocks access to biological material for further breeding which material otherwise would be free for such purposes under plant variety protection.

This uncertainty concerning the freedom to operate, and possibly reduced availability of plant genetic material for further breeding, practically affects the day-to-day work of plant breeders, although there are no data publicly available regarding to what extent breeders have actually tried to obtain a licence from a patent holder.

When starting their breeding programs breeders should be able to know whether the biological material they intend to use falls under the scope of a patent application or a granted patent. The scope of a patent (or a patent application) is determined by the claims. However, patent claims may be very broad and in most cases it is almost impossible for a breeder to know whether a particular plant variety is covered by a specific patent or not. In practice, it is often only the developer of the variety who is able to tell whether a variety is covered by a patent or not.

Further, one patent may cover many varieties, as well as covering varieties in several crops (e.g. patents on Brassica plants may easily cover cabbage, cauliflower, broccoli and other crops). Thus, the number of granted patents or patent applications in the field of plant-related inventions does not necessarily correlate well with the impact of such patents on breeding work since the impact of only few patents can already be significant. In addition to the above, the fact that the patent granting

¹⁵ A dissenting opinion is provided (Annex III), see Chapter 10 therein.

procedure typically takes a few years and the scope of the claims of the granted patent may not be entirely clear at the outset adds to the uncertainty breeders have. While the latter applies to other fields as well, as breeders ideally would need to start with the broadest possible diversity during the breeding process makes it a recurrent issue for them.

Given the uncertainty about the patented status of biological material and thus the freedom to operate, breeders might be discouraged to make use of one or the other material. This could reduce the genetic variability of the starting material.

Even when there is no uncertainty but it is clear that a variety is covered by the scope of a patent, its availability for further breeding and development is not guaranteed since – in most of the cases still – the act of use for further breeding requires a license. If such licence is not obtained or is not taken up because it is regarded as prohibitively expensive, this also leads to material being excluded from the breeding process.

Importantly, although the reduced variability of starting material leading to fewer and less diverse varieties is a repeatedly expressed concern by the breeder sector, at this point in time there is no evidence yet that it leads to a reduced number of varieties being applied for or entering the market. There are approximately 35-40 000 varieties available on the market in the EU and some 3 500 new varieties are added to this pool on a yearly basis¹⁶. The Community Plant Variety Office (CPVO), in its last available annual report, states that 2013 was a record year with the highest level of applications. The feared decrease is thus not, or not yet, evident from the number of registered plant varieties¹⁷. Granted, it is expected that the effect of companies stopping breeding programs because they cannot get access to genetic material, will only become noticeable after a period of time, as developing new varieties takes 7 to 15 years, depending on the crop. Nevertheless, as seen from Table 2.1, patent applications for plant-related inventions were already filed over 15 years ago.¹⁸

Some national patent laws have recently provided exemptions to ensure the free use of biological material for further breeding¹⁹, but the commercialization of a new plant variety incorporating the patented invention will still require a license from the patent holder. The latter is of course true for every commercial product incorporating patented material.

Where an interface does exist between the two systems for legitimate reasons, breeders urge that pragmatic solutions need to be found ensuring the availability of plant genetic material for further breeding while finding the right balance between the interests of patent holders and licensees.

¹⁶ See the common catalogues of varieties of agricultural plant and vegetable species, published in the Official Journal.

¹⁷ It should be noted that there is a distinction between the registered varieties, and the varieties that are marketed: not all registered varieties enter the market. It is thus possible that fewer varieties are marketed even if registration numbers are stable. However, at this point in time, no decreasing trend is observed for varieties on the market either (see footnote 9).

¹⁸ A dissenting opinion is provided (Annex III), see Chapter 8 therein.

¹⁹ In German, French, Swiss and Dutch patent laws such an exemption exists and draft legislation has been proposed in the UK to implement this in the UK Patent Act. See Annex I.

1.4 Brief overview of the technological developments and evolutions in the last decade in the field of plant breeding

As indicated above, molecular biology tools and methods have enhanced the possibilities of plant breeders for generation of new plants. It is not the intention to provide an exhaustive overview of these methods here - as this is a very active field, every overview is just a snapshot in time. By way of illustration, a table is presented listing some of the techniques that either were developed in the last decade, or became more relevant. The majority of these techniques is discussed in the JRC report on new plant breeding techniques²⁰ and we refer to this publication for technical details on these techniques.

Apart from Zinc finger nucleases, a number of other techniques relying on nucleases have been further developed since the publication of the JRC report in 2011.

Meganucleases are endodeoxyribonucleases characterized by a large recognition site (double-stranded DNA sequences of 12 to 40 base pairs); as a result this site generally occurs only once in any given genome. By modifying the specificity of existing meganucleases and/or developing chimeric meganucleases with a new recognition site, tailor-made meganucleases can be created.

Transcription activator-like effector nucleases (TALENs) are artificial restriction enzymes generated by fusing a TAL effector DNA-binding domain to a DNA cleavage domain. Restriction enzymes are enzymes that cut DNA strands at a specific sequence. Transcription activator-like effectors (TALEs) can be quickly engineered to bind practically any desired DNA sequence. By combining such an engineered TALE with a DNA cleavage domain (which cuts DNA strands), one can engineer restriction enzymes that are specific for any desired DNA sequence.

Generally regarded as a ground breaking technique, the CRISPR/Cas system has recently been developed for gene editing, also in plants²¹. Despite the fact that it was only developed very recently, this technique is widely considered to have a high potential to become one of the most preferred genome editing techniques.

Briefly, the CRISPR/Cas system is a RNA-guided DNA targeting system that allows adding, disrupting or changing the sequence of specific genes at any desired location. CRISPRs (clustered regularly interspaced short palindromic repeats) are segments of DNA containing short repetitions of base sequences that naturally occur in prokaryotes as part of their immune system. They work in concert with CRISPR-associated (Cas) genes that encode nuclease proteins. When CRISPR RNAs (crRNAs) are transcribed from the CRISPR locus, the crRNAs are then incorporated into effector complexes, where the crRNA guides the complex to a particular nucleic acid and the Cas proteins degrade this nucleic acid. The specificity of the system to guide RNA to the target site relies on base pairing.

²⁰ New plant breeding techniques. State-of-the-art and prospects for commercial development. Maria Lusser, Claudia Parisi, Damien Plan, Emilio Rodríguez-Cerezo (2011) EUR Number: 24760 EN

²¹ See e.g. Shan Q, et al.: Targeted genome modification of crop plants using a CRISPR-Cas system. *Nat Biotechnol* (2013), 31:686-688.; Li JF, et al.: Multiplex and homologous recombination-mediated genome editing in *Arabidopsis* and *Nicotiana benthamiana* using guide RNA and Cas9. *Nat Biotechnol* (2013), 31:688-691.; Nekrasov V, et al.: Targeted mutagenesis in the model plant *Nicotiana benthamiana* using Cas9 RNA-guided endonuclease. *Nat Biotechnol* (2013), 31:691-693.; Feng Z, et al.: Efficient genome editing in plants using a CRISPR/Cas system. *Cell Res* (2013), 23:1229-1232

By making appropriate synthetic guide RNAs and delivering these together with a Cas protein (typically Cas9) to a cell, the organism's genome can be cut at any desired location.

Zinc-finger nucleases, meganucleases and TALENs depend on making custom proteins for each DNA target. As the synthesis of a guide RNA based on nucleic acid complementarity is less complex than generating a custom protein, the adoption of the CRISPR/Cas technique is expected to surpass the other nuclease techniques.

Finally, marker-assisted breeding is included in the table, not because it is a recent technique, but because it is still the most widely applied molecular technique in plant breeding.

Table 1.1 Overview of select molecular techniques in the field of plant breeding during the last decades

Technique	Is the technique part of technological developments in the past decade in the field of plant breeding?	First publication in scientific literature	Relevance in plant breeding	Crops where used	Remarks
Oligonucleotide directed mutagenesis (ODM)	YES	1999	YES	Rapeseed; sunflower; linseed; flax	The first rapeseed varieties with herbicide tolerance based on ODM are already marketed in the US and received regulatory approval in Canada
Zinc finger nuclease (ZFN) technology	YES	1996 Related to application in the field of plants: 2005	YES	Sunflower; linseed; flax; tobacco; maize	In most crops mentioned the use so far is in R&D only but in maize the technique has been used in applied plant breeding (i.e. leading to commercial products) since approx. 5 years.
Transcriptor activator-like effector nucleases (TALENs)	YES	2009	YES	Rapeseed; sunflower; linseed; flax; potatoes; vegetables; rice	Use in R&D only (mainly due to unclear regulatory environment).
Clustered Regularly Interspaced Short Palindromic Repeats / CRISPR associated genes (CRISPR/Cas)	YES	2013	YES	Rapeseed; linseed; flax; rice; wheat	Use in R&D only. Applications of this technique in wheat and rice have been published (and patented) in July 2013.
Meganuclease technique	YES	2008	NOT YET	maize	Not yet used in applied plant breeding mainly due to unclear regulatory environment.
Cisgenesis and intragenesis	YES	2004	YES	Linseed; flax; apples; potatoes; cereals	In apples, potatoes and cereals the technique seems to have been used also in applied plant breeding since a few years. Field

					trials of Phytophthora resistant potatoes were done in Belgium in 2011-12 and the Netherlands in 2014.
RNA-dependent DNA methylation (RdDM)	NOT YET	1999 (or 1994)	Not very relevant		The gene silencing effect in this technique fades away after several generations. This point needs further investigation before the technique can be used in practical breeding.
Reverse breeding	YES	2006	NOT YET	vegetables	Not yet used in applied plant breeding mainly due to unclear regulatory environment.
Agro-infiltration	YES	1986 (basic concept of the technique already described)	YES	Rapeseed; vegetables; potatoes	This technique is relevant in screening and disease testing procedures in plant breeding but it is not a breeding technique in itself.
Synthetic genomics/Synthetic biology	NOT YET	First synthetic bacterial genome described in 2008, no applications in plants yet.	NO		Synthetic genomics may be understood as “engineering of biological components and systems that do not exist in nature and the re-engineering of existing biological elements”. This technique so far however has not come to concrete studies or applications in plant breeding.
Marker-assisted breeding	NO	1983 (molecular markers)	YES	All crops in applied plant breeding	Marker-assisted selection/breeding is already widely used in all crops since decades.

Chapter 2. Essentially biological processes for the production of plants

2.1 Introduction

In the Biotech Directive, inventions which concern plants are deemed patentable if the technical feasibility of the invention is not limited to a variety (Art 4(2) Biotech Directive). For plant varieties, protection can be obtained through Plant Variety Right (PVR). Essentially biological processes for the production of plants are not deemed patentable.

When discussing patents on plant-related inventions, the discussion in the first years centred on plants obtained by genetic engineering²². Indeed, the number of patents on plant-related inventions increased when this technology became available. It should be kept in mind, however, that the entry into force of the European patent convention predates the first transgenic plant by 10 years.²³

Although there is controversy surrounding genetic engineering of plants in the EU, this is predominantly for non-patent related reasons. Rather, public policy arguments have been forwarded to object to those patents. From a pure patent perspective, both the processes to produce such plants and the resulting plants did not exist before, contain a clear technical step and thus are less controversial in terms of patentability. Indeed, in the area of plants, most patent applications relate to genetically engineered (GM) plants (Fig. 2.1) and typically concern characteristics such as improvements in yield, higher nutritional value or resistance to drought and pests. As a general remark however, both the scope and the number of patents may be relevant²⁴.

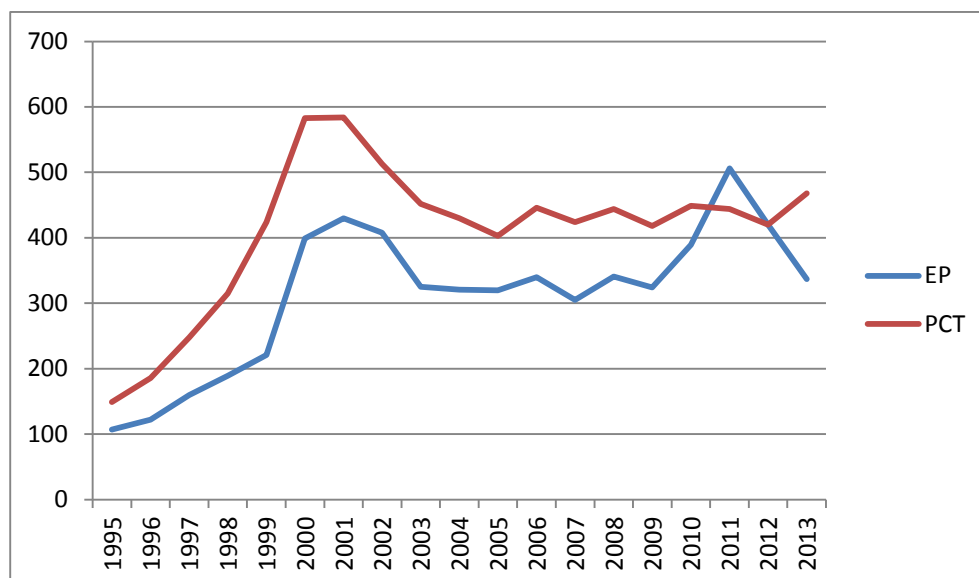


Figure 2.1. Number of published applications per year for GM plants (Source: EPO)

²² See e.g. the discussion of G1/98 offered in T1854/07.

²³ A dissenting opinion is provided (Annex III), see Chapter 2 therein.

²⁴ An example in breeding are so-called “must have-traits”. A “must have-trait” is a trait that varieties of a certain species should have, otherwise the varieties will not be used. For example, a resistance against a pest could be a must have-trait in a crop. If such a trait is patented, this will be just one patent, but affects all varieties in the crop(s). If a breeder cannot obtain a license, or this is still unsure, the risk of starting a costly breeding process is too high, as it cannot be predicted whether this will result in a new and commercially viable variety.

In recent years, the EPO has also received a number of patent applications relating to plants obtained by breeding processes that do not involve genetic engineering but are i.a. based on conventional breeding (Fig. 2.2)²⁵.

A comparison of an estimated number of published patent applications per year for non-GM and GM plants is given in Table 2 (Figure 2.1 and 2.2 are taken from these data).

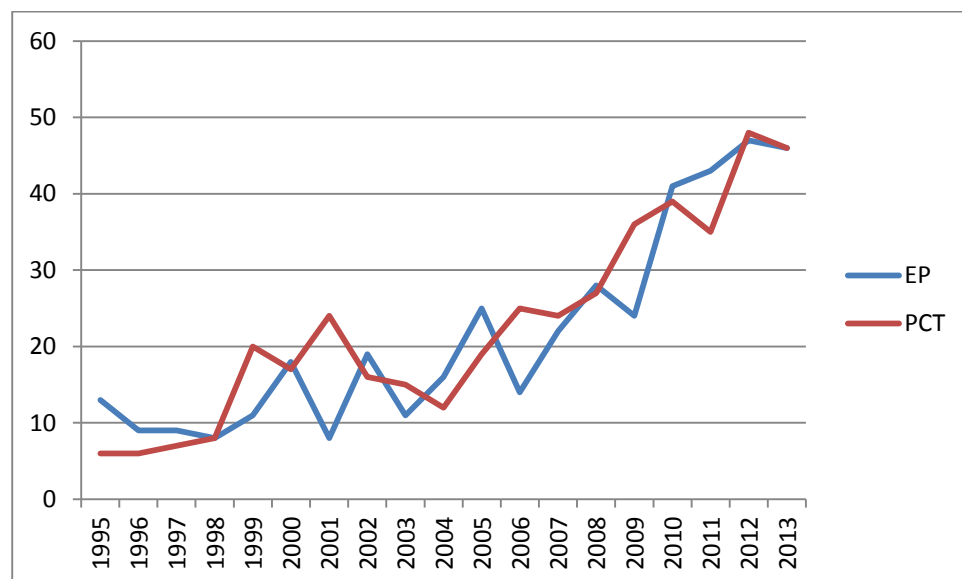


Figure 2.2. Number of published applications per year for non-GM plants (Source: EPO)

²⁵ Figure 2.1 and 2.2 relate to published applications. This does not necessarily correlate to granted patents, and does not form an indication of whether plants are marketed that fall under the scope of these applications.

Table 2.1 Comparison of number of published applications per year for conventional and GM plants.

Year	GM plants		Conventional plants	
	EP	PCT	EP	PCT
1995	107	149	13	6
1996	122	186	9	6
1997	160	248	9	7
1998	189	315	8	8
1999	221	424	11	20
2000	399	583	18	17
2001	430	584	8	24
2002	408	513	19	16
2003	325	452	11	15
2004	321	430	16	12
2005	320	403	25	19
2006	340	446	14	25
2007	305	424	22	24
2008	341	444	28	27
2009	324	418	24	36
2010	389	449	41	39
2011	506	444	43	35
2012	420	420	47	48
2013	337	468	46	46

The field of plant breeding traditionally relies on plant variety rights (PVR), even though the option of patenting of plant-related inventions has always been available in the EPC. The PVR system however only allows for the protection of individual plant varieties as such but not of larger groups of plants or other innovations, such as tools used in breeding, for which the patent system offers protection possibilities. Many companies, including most larger companies, active in the field of plant breeding, use both the PVR and the patent system.

As outlined in the section on recent developments above (Chapter 1), multiple new technologies have been developed (and are still being developed) in the field of plant breeding. Many of the recently developed techniques are clearly technical in nature, especially if they involve the insertion of heterologous material into cells and thus contain a step that by itself (without the sexual crossing of whole genomes) introduces or modifies a trait in the genome. Several of those techniques have not been put into commercial practice yet, but are not likely to raise new questions in regard to patentability of plant related inventions.

However, some breeding techniques combine new molecular insights with traditional breeding practices, and use molecular techniques not to introduce or modify a plant trait, but e.g. as a marker to select particular plants with a desired characteristic. The question has arisen as to whether these technologies are patentable, or whether they fall within the category of essentially biological processes.

For the purposes of the question as to the patentability of essentially biological processes and the products thereof, marker assisted breeding can be taken as a good example. Although not really a recent technological development in the field of plant breeding (since it was already applied in the nineties of last century), marker assisted breeding is probably one of the, if not the, most relevant commercial technologies making use of molecular information, and applied in plant breeding, for the last two decades. Although widely adopted in breeding practice, the patenting of processes based on crossing and selection (such as marker assisted breeding) has met with resistance, both from breeders and from NGOs. Opposition against patents led to decisions G2/07 (“Broccoli”)²⁶ and G1/08 (“Tomato”)²⁷ of the Enlarged Board of Appeal (EBoA) of the EPO, which clarified that such processes are not patentable.

A large part of the concerns relates to differences between the PVR and the patent system, particularly with regard to the breeders’ exemption. While this exemption in the PVR allows breeders to use protected varieties as sources of initial variation to create new varieties of plants, such exemption is lacking in the patent system. It is therefore perceived that patents have a blocking effect on the availability of genetic material for further breeding. The interaction between patents and PVR and the breeders’ exemption will be discussed separately further in the report (Chapters 4 and 5 respectively).

A further argument is based on the underlying technology: patenting breeding methods that do not differ much from what breeders have been doing for decades should not be allowable because these methods are essentially biological processes.

This brings us to the question as to what is an essentially biological process.

2.2 Relevant legal provisions²⁸

Relevant provisions of the Biotech Directive:

Art. 2(2): A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

Art. 4(1): The following shall not be patentable: (...)

(b) essentially biological processes for the production of plants or animals.

Art. 4(3): Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Other legal provisions:

²⁶ The underlying patent, EP1069819, claims methods for production of *Brassica oleracea*, comprising steps of crossing and selection, wherein molecular markers are used to identify desired hybrids, and contains claims to the plants *per se*.

²⁷ The underlying patent, EP1211926, claims methods for breeding tomato plants that produce tomatoes with reduced fruit water content, comprising crossing and selection steps, followed by allowing fruit to remain on the vine until it is partially dried; and claims the plants *per se*. Of note, it does not relate to marker assisted breeding.

²⁸ The overviews on legal framework provided in the different chapters are by no means meant to be exhaustive, they merely list the articles that are considered to be of particular relevance for the topic under discussion.

Art. 53(b) EPC: *“European patents shall not be granted in respect of: (a) [...]; (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof; [...]*”

Rule 26(5) EPC is identical to Art. 2(2) of the Biotech Directive.

2.3 The term essentially biological processes

Defining what an essentially biological process is seems to be the most obvious way forward with a view to provide legal certainty. Although the provision in the Biotech Directive is clear enough at first glance, a closer look shows that the boundaries are not that well-defined, and it seems difficult to use in practice because of a lack of clarity.

In its decision G2/07 on essentially biological processes, the Enlarged Board considers the Biotech Directive and its legal history in the hope of further clarifying the meaning to be given to Rule 26(5) EPC²⁹. This turns out to be a dead end (the EBoA went so far to say that the provision in the Biotech Directive is unclear and contradictory³⁰), and the Enlarged Board concludes that the contradiction between the terms of the provision is not further clarified by the legislative history of the Biotech Directive. The Enlarged Board therefore comes to the conclusion that Rule 26(5) EPC does not give any useful guidance on how to interpret the term “essentially biological process for the production of plants” in Article 53(b) EPC.

Although the board in G2/07 further holds that “[a]ny attempt to determine a reliable literal meaning for the term “essentially biological” process appears futile”³¹, an elaborate attempt is made to see how the term should be construed. The EBoA interprets the term on its own authority and in doing so, the Enlarged Board goes all the way back to 1961 in seeking the legislator’s original intention with this Article. It is concluded that what was intended to be excluded from patentability was the kind of breeding processes applied by plant breeders in connection with the creation of new plant varieties, for which a special property right was to be introduced under the UPOV Convention. Additionally, the board notes that “essentially biological processes” are not “purely biological processes”, in that technical means may be used in them: *“The exchange of the word “purely” for “essentially” was deliberate and reflects the legislative intention that the mere fact of using a technical device in a breeding process should not be sufficient to give the process as such a technical character and should not have the effect that such process is no longer excluded from patentability.”*³²

Thus, the board states that *“the conclusion to be drawn is that a process for the production of plants which is based on the sexual crossing of whole genomes and on the subsequent selection of plants, in which human intervention, including the provision of a technical means, serves to enable or assist the performance of the process steps, remains excluded from patentability as being essentially biological within the meaning of Article 53(b) EPC.*

²⁹ G2/07, reasons 4.7 – 4.8

³⁰ G2/07, reasons 4.8.3

³¹ G2/07, reasons 6.1.3

³² G2/07, reasons 6.4.2.3

*However, if a process of sexual crossing and selection includes within it an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then that process leaves the realm of the plant breeding, which the legislator wanted to exclude from patentability.*³³(emphasis added)

Apart from the G2/07 decision, there is little guidance to be found on interpretation of the term.

The CJEU has presently not expressed itself on the matter.

Despite the thorough and extensive analysis of the EBoA, the Expert Group found agreement on the fact that the conclusion of the EBoA in G2/07 did not provide an exhaustive definition of what is an essentially biological process. That has also been confirmed in recent case law from the TBA.³⁴

Within the Expert Group, agreement could be reached that Headnote 1 and 2 of G2/07 constituted valuable and valid elements of a definition of what is an essentially biological process. No agreement could be reached, however, on the usefulness of the further headnotes in defining what an essentially biological process is.

Headnote 1 reads: “A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being “essentially biological” within the meaning of Article 53(b) EPC.”

Headnote 2: “Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.”

Headnote 3: “If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.”

Headnote 4. “In the context of examining whether such a process is excluded from patentability as being “essentially biological” within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.”

With respect to the third and fourth headnote, dissenting arguments were presented in particular regarding breeding processes for producing plants having traits modified by techniques such as chemical or radiation mutagenesis and a common position could not be reached. The Expert Group

³³ G2/07, *ibidem*

³⁴ T 1729/06, reasons 19: “(...)the board notes that, on the other hand, the Enlarged Board of Appeal has not, in these decisions, given a comprehensive and exhaustive definition of the subject-matter to which the process exclusion in Article 53(b) EPC applies in relation to plant inventions.”

made a distinction between three types of mutagenesis: natural mutagenesis (i.e. spontaneous mutations, naturally occurring e.g. as result of molecular decay, DNA repair errors, and the like), random mutagenesis (defined here as the introduction of mutations by the purposeful contact with a mutagen), and targeted or site-directed mutagenesis (which introduces selected changes to DNA in a site-specific manner). All Experts could agree that natural mutagenesis is a natural process, and that targeted mutagenesis is a technical process. Although the majority of the Experts agreed that inducing mutagenesis by chemicals or radiation is a technical step, a minority sees it as a mere acceleration of a natural process. Interestingly, radiation mutagenesis was explicitly deemed patentable in the first Preliminary Draft Convention³⁵, and since this technique introduces mutations without sexual crossing, G2/07 seems to reiterate that this technique is not excluded from patentability.

As G2/07 left the members still divided on the boundaries of the term “essentially biological processes”, common ground was sought. It was agreed that:

- Breeding techniques based on the sexual crossing of whole genomes and subsequent selection, are not patentable (the definition provided in G2/07, a minimal definition for essentially biological processes);
- A process such as targeted or directed mutagenesis is patentable, since it is a technical process that produces plants through targeted genetic modification and not by the mixing of whole genomes and consequently does not fall under the first headnote of EBoA decision G2/07;
- Directive 98/44/EC and decision G2/07 leave a grey area.

The extent of this grey area is unclear, and likely to be a moving target. Most Experts agreed that, at least at present, the area of uncertainty is likely quite small. By way of illustration, a table (Table 2.2) is provided that lists the techniques discussed in the technological development section of Chapter 1 (in Table 1.1), and how the criteria of G2/07 apply to these techniques. Of note, it seems likely that the most contentious techniques are not those newly developed in the last decade (as many of them are without a doubt technical processes).

Table 2.2. How the criteria of G2/07 apply to the techniques of Table 1.1

Technique	Requires crossing of whole genomes to introduce trait	Contains technical step that by itself (without crossing) introduces or modifies a trait in the genome
Oligonucleotide directed mutagenesis	No	Yes
Zinc finger nuclease (ZFN) technology	No	Yes
Transcription activator-like effector nucleases (TALENs)	No	Yes

³⁵ G2/07, reasons 6.4.2.3 “processes changing the genome of plants by technical means such as irradiation are cited as examples of patentable technical processes”.

CRISPR/Cas systems (<u>C</u> lustered <u>R</u> egularly <u>I</u> nterspaced <u>S</u> hort <u>P</u> alindromic <u>R</u> epeats / <u>C</u> RISPR associated genes)	No	Yes
Meganucleases	No	Yes
Cisgenesis and intragenesis	No	Yes
RNA-dependent (or RNA-directed) DNA methylation (RdDM)	No	Not applicable: change is epigenetic and lost after a few generations
Reverse breeding	Yes	Yes, intermediate step requires RNAi-mediated suppression of meiosis.
Agro-infiltration	No	When no germline cells are present (e.g. leaves), then no: overexpression is transient When germline cells are present (e.g. flowers): yes
Synthetic biology / synthetic genomics	No (hypothetically, to our knowledge no plant has yet been created using this technique)	Yes
Marker-assisted breeding (MASB)	Yes	No

As can be seen from the table, almost all breeding techniques listed in the table pass the test proposed in G2/07, as they either contain a technical step wherein a trait is introduced or modified (without crossing), or, if this is unclear or not applicable, the techniques don't require the crossing of whole genomes to introduce the trait. The only technique that fails the G2/07 test for patentability is MASB.³⁶

After extensive discussion, a large majority of the Experts came up with two examples that are not easily classified using the G2/07 criteria: embryo rescue³⁷ and protoplast fusion³⁸. In general, the

³⁶ A dissenting opinion is provided (Annex III), see Chapter 5 therein.

³⁷ In the case of interspecific crosses, the embryo formed after fertilisation frequently fails to develop. When applying the technique of embryo rescue, the ovary is excised within several days after fertilisation to avoid abortion. The embryo is then nurtured into a full plant using *in vitro* tissue culture.

criterion of sexual crossing of whole genomes may be difficult to apply for generation of hybrid plants. Likewise, introducing or modifying a trait in the genome outside of sexual crossing may be difficult to judge for hybrid genomes. Both techniques have however already been used for decades in plant breeding.

In the aftermath of G2/07, the only decision³⁹ of the Technical Boards of Appeal that also deals with essentially biological processes, T1729/06, was issued. The patent application at issue in that case⁴⁰ related amongst others to methods for producing triploid, seedless watermelon fruit, comprising planting a field with [sterile] triploid watermelon plants; allowing pollination by pollen of diploid plants; and harvesting seedless watermelon fruit.

The application was refused by the Examining Division as claiming subject-matter that is an essentially biological process for producing plants⁴¹. The Board of Appeal disagreed, stating that the methods were in fact methods for producing fruits on existing plants, did not aim at the creation of any genetic make-up of any plant produced as the result of meiosis, and that *“the use and methods do not involve successful meiosis in the triploid plant flowers. Rather, they merely concern the pollination of the sterile female flowers of the triploid watermelon plant with pollen of the diploid polliniser plant. They do not concern sexually crossing two whole genomes of plants (implying meiosis and fertilisation) and the subsequent selection of plants.”* (T1729/06, reasons 17)

In discussing the term essentially biological processes, the board *“concludes that the EPC 1973 legislator (and hence the EPC 2000 legislator) only wished to exclude from patentability, in the context of the process aspect of the exclusion in relation to plant inventions, the -then conventional - processes applied by plant breeders in connection with new plant varieties for which a special property right was available under the UPOV Convention and processes which were fundamentally of this type.”* (T1729/06, reasons 32)

The decision concludes that fruit production and pollination are biological processes, but are not breeding methods. In the English version, the exclusion of Art. 53(b) EPC relates to essentially biological processes for the production of plants (which could be deemed to cover breeding and non-breeding processes such as growing plants). The French and German versions of this provision relate to breeding of new plants and do not cover non-breeding processes (the exclusion refers to ‘les procédés essentiellement biologiques d’obtention de végétaux’ and ‘Wesentlichenbiologische Verfahren zur Züchtung von Pflanzen’, respectively). The Board held that the purpose of Article 53(b) was to exclude conventional breeding processes (see above), not processes such as those of the application in suit, which are not a breeding method involving successful meiosis (crossing of whole genomes).

It seems to be difficult indeed to come with an all embracing definition of what is an essentially biological process. Since we do not know what future processes for producing plants may emerge,

³⁸ Protoplasts are produced by removing the cell wall from plant cells using either mechanical or enzymatic means. Protoplast fusion entails that protoplasts (most often from two different species) can be fused to create a hybrid. The fusion can be accomplished by an electrical process or by chemical agents.

³⁹ Issued 17 September 2014

⁴⁰ European application No. 03744126.8

⁴¹ The claims at the basis of the refusal related only to methods and uses relating to fruit production or yield, not to the plants or fruits themselves, nor to methods for producing plants.

any attempt to come up with a comprehensive definition would probably be doomed to failure.⁴² Patent law can never provide absolute clarity, as it must regulate an indefinite number of concrete cases in an abstract manner and regularly adapt to technological developments. What the EPO's Enlarged Board of Appeal has done with G2/07 is to establish general criteria for determining when a process is to be seen as essentially biological, leaving the decision for specific cases to the EPO's first instances and technical boards of appeal.⁴³

2.4 Conclusion on essentially biological processes for the production of plants

In conclusion to this point, a review of the statutory and case law framework and the problems and issues faced with in the light of recent technological developments seem to indicate both that there is a grey area with regard to what exactly are 'essentially biological processes', and that there are at present few cases within this grey area.⁴⁴

Importantly, the uncertainty about the scope of 'essentially biological processes' is not a direct result of the breeding techniques developed in recent years (Chapter 1) and that contain technical steps that introduce or modify a trait in the genome without crossing. On the contrary, it may be more relevant for cases that combine classical breeding with some technical element. It is thus not a new problem, but has been brought to the forefront by an increase in patenting in the field of plant-related inventions. This does not exclude the possibility that new techniques will be developed that may raise new questions on the scope of "essentially biological processes".

Recommendations

As for each chapter, there are three categories of recommendations the Experts could make, here indicated with the option and the number of Experts who support it:

- 1) Taking no action (13 of 15)
- 2) Request a clarifying statement by the Commission (2 of 15)
- 3) Recommend legislation to make clear what is unclear:
 - as separate legislation (2 of 15, as first fall-back option)
 - by reopening the Directive (2 of 15, as second fall-back).

⁴² A dissenting opinion is provided (Annex III), see Chapters 5 and 6 therein.

⁴³ In two different fields of technology different attempts have been made to provide a definition of a term. In G1/07, relating to methods of treatment of the human or animal body by surgery, expressly did not attempt to delimit the exact boundaries of the new, more limited interpretation it held to be appropriate for the exclusion. On the contrary, that ruling also confined itself to setting out general criteria to be used for deciding whether a specific method is to be viewed as surgical or not. G1/07 asserted that the first instance bodies and the boards of appeal were much better suited to define the boundaries of a more narrowly construed concept of "treatment by surgery" in situations other than the one underlying G1/07, based on the technical reality of the individual cases under consideration (see G1/07, Reasons, 3.4.2.4). There are other areas of technology where it has proved impracticable to define an exclusion from patentability so comprehensively as to provide clarity as what is patentable and what is not. Computer related inventions, as they are called within the case law of the EPO, is one such area. Although the EPO's extensive case law on the subject, reviewed in G 3/08, has provided useful guidance on the patentability of such inventions, individual cases still arise in which a clear definition of what is technical requires critical scrutiny.

⁴⁴ A dissenting opinion is provided (Annex III), see Chapter 5 therein.

A large majority (all but two) of the Expert Group recommends that no action is taken to address the term “essentially biological processes”. These Experts are of the opinion that no action is required as the law already provides for an exclusion of “essentially biological processes” and further clarification is and will be given by case law.

A minority view taken by two Experts is that a clarifying statement of the Commission is in order to make sure conventional breeding, including essentially biological processes, is not covered by patent protection. These Experts made stepwise recommendations: if such a clarifying statement is not feasible, or not sufficient to reach legal certainty, legislative action is needed, preferably in the form of separate legislation (outside of the Biotech Directive). If this is also insufficient, reopening the Biotech Directive is a second fall-back option in the view of these two Experts.

Chapter 3. Products obtained by essentially biological processes

3.1 Introduction

The patentability of claims covering products and claims covering processes to produce these products are typically dealt with separately since it is a general principle of patent law and e.g. also the scope of the claims and the respective prior art may differ significantly. Indeed, it is possible that new, patentable products are made using trivial processes, and vice versa, that a completely novel process is used to make an existing product. Nonetheless, the two are interrelated⁴⁵. Thus, the question arises whether the exclusion from patentability of essentially biological processes for the production of plants (as decided in G2/07 and G1/08) can have a negative effect on the allowability of a product claim to genetic material (e.g. plants and plant parts).

This very question was referred to the EPO's enlarged Board of Appeal.

During the further prosecution of the two patents that were the subject of referrals G2/07 and G1/08, the Technical Board of Appeal decided to refer new questions to the Enlarged Board of Appeal relating to the patentability of plants obtained by essentially biological processes. The board pointed out that a patented product enjoyed absolute protection for the product itself, and also for all its uses and processes for making it, whereas a claim to a process conferred a narrower scope of protection, namely only for the process plus its direct products under Article 64(2) EPC. Concerns were expressed that allowing claims to plants made by an excluded essentially biological process (EBP) would allow the patent proprietor to stop others using the non-patentable EBP taught by the patent: products of processes breeders are performing would fall under patent scope and breeders would not be able to commercialise the plants obtained by the essentially biological process. Fears have been presented that this might frustrate the legislator's intentions and make the circumvention of the exclusion of EBP a matter of skilful claim drafting.

The Board considered that the earlier referral **G1/98** (OJ EPO 2000, 111) had not addressed this issue, since the referral case concerned transgenic plants, not plants produced by crossing and selection⁴⁶.

The most important question referred reads as follows:

1. Can the exclusion of essentially biological processes for the production of plants have a negative effect on the allowability of a product claim to plants or plant material such as plant parts?

The further questions related to particular consequences on the interplay of product claims relating to plants or plant material and the exclusion of essentially biological processes from patentability:

⁴⁵ E.g. in European Parliament resolution of 10 May 2012 on the patenting of essential biological processes (2012/2623(RSP)) the G2/07 and G1/08 decisions on patenting of essentially biological processes are welcomed, and the EPO is called upon also to exclude from patenting products derived from conventional breeding and all conventional breeding methods.

⁴⁶ See the second referral decision in case T1242/06, points 40 to 66 of the reasons; and the second referral decision in case T0083/05, points 17 to 20 of the reasons for the full arguments.

2. In particular, is a claim directed to plants or plant material other than a plant variety allowable even if the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application?

3. Is it of relevance in the context of questions 1 and 2 that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC?⁴⁷

3.2 Relevant legal provisions

Relevant provisions of the Biotech Directive

Art. 3(2): Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 4 (1): The following shall not be patentable:

(...)

(b) essentially biological processes for the production of plants or animals.

Art. 4(2): Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

Art. 4(3): Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Art. 8(2): The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

Other legal provisions

Rule 27(b) EPC: Biotechnological inventions shall also be patentable if they concern: (...) (b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety; (...)

Art. 64(2) EPC: If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.

3.3 Decisions G2/12 and G2/13

The Enlarged Board of Appeal has delivered its decisions on the above mentioned referrals on 25 March 2015, during the drafting of this report. The decisions (G2/12 or “Tomato 2” and G2/13 or “Broccoli 2”) answer the questions as follows:

⁴⁷ A fourth question was referred in G2/13 only, relating to the possibility of a disclaimer if product claims directed to plants or plant material were considered not allowable. In view of the reply to the other questions, this question was not answered by the EBoA.

1. The exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as plant parts.

2(a). The fact that the process features of a product-by-process claim directed to plants or plant material other than a plant variety define an essentially biological process for the production of plants does not render the claim unallowable.

2(b). The fact that the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application does not render a claim directed to plants or plant material other than a plant variety unallowable.

3. In the circumstances, it is of no relevance that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC.

The Enlarged Board stated that any exception to patentability must have a clear legal basis (Reasons VII.2.3). They analysed the situation in detail and concluded that neither the EPC nor the Directive provided a basis for extending the exclusion of essentially biological processes to the plants produced by such methods (Reasons VII.4.3). While explicitly acknowledging the ethical, social and economic aspects in relation to the patentability of plants, the EB made it clear that it is competent only to interpret the EPC, not to engage in legislative policy considerations (Reasons VIII.2.6(c)). The EB also rejected the argument that patenting the products of EBP amounted to skilful claim drafting and an evasion of the process exclusion, rather describing this as a legitimate choice to obtain patent protection (Reasons IX.4). However, the EB emphasised that the plant products would have to fulfil all patentability requirements, and that these were particularly strict for product-by-process claims (*ibidem*).

3.4 Brief analysis of the consequences

The consolidated Decisions of these two cases are quite clear in ruling that the exclusion of essentially biological processes for the production of plants does not have a negative effect on the allowability of a claim for plants or plant material. Nevertheless, above and beyond the purely legalistic aspects (which were tackled by the EPO), the Expert group can highlight which aspects of practice and/or the biotech directive are likely to be affected by these decisions.

Concerns have been voiced that, since plants obtained by an essentially biological process are deemed patentable, this might limit the exclusion from patentability of the essentially biological processes for the production of plants. Indeed, as stated in G2/07, the legislator intended to exclude conventional methods for breeding plant varieties. Allowing claims to plants made by an excluded essentially biological process would thus allow the patent proprietor to stop others using the non-patentable EBP taught by the patent: products of processes breeders are performing would fall under patent scope and breeders would not be able to commercialise the plants obtained by the essentially biological process.

Despite these concerns, a patent on a plant obtained by an essentially biological process is *in se* not at odds with the Biotech Directive: Art. 4(2) allows patents on plants if the technical feasibility of the

invention is not confined to a particular plant or animal variety, i.e. irrespective of the technique used to create the plant.⁴⁸

The view was expressed that, because of the fact that non-patentable essentially biological processes now effectively can fall under the scope of product patents, it would have been more consistent if patents on plants obtained by essentially biological processes were not allowed as this would have helped in providing access to biological material to breeders for the purpose of further innovation.

It was pointed out however that, in theory, an identical plant (or a plant that is at least identical in claimed characteristics) can be made using different techniques. Some exceptions notwithstanding, it is in general not possible to derive which method was used to create a plant. Thus, if not now, then in the near future, the distinction between plants obtained by essentially biological processes and plants obtained by technical processes cannot always be made.⁴⁹

A specific aspect of plants that adds another layer of complication in the patenting discussion is that plants are self-propagating. This means in practice that a gene or characteristic can be transferred from one generation to the other, and that not necessarily the same technique needs to be used. For instance, a transgenic plant can cross with another identical transgenic plant using methods relying on crossing of whole genomes, while the progeny is still a transgenic plant.⁵⁰ This particularity has been addressed in the Biotech Directive in Article 8(1), stating that the protection of a patent shall extend to biological material that is derived through propagation or multiplication in an identical or divergent form and possessing the same characteristics (that result from the invention).

It seems that the underpinning problem cannot be resolved by expanding the exclusion of essentially biological processes from patentability to products obtained by such processes. As explained, even genetically engineered products can be made by essentially biological processes. The legislator's intent seems to be to exempt from patentability conventional methods for breeding plant varieties which are solely based on naturally occurring genetics and which have been combined by sexual crossing. However even with such a definition the burden of proof of what is pre-existing in nature and what is man-made could be complex, as the products can still be identical.⁵¹

Some Experts disagreed with the conclusions of the Enlarged Board of Appeal in G2/12 and G2/13, particularly as it limits access for breeders to patented material.⁵² Within the Expert Group, the hypothetical situation was discussed whether excluding plants obtained by essentially biological processes from patentability would have been enough to ensure this access.

⁴⁸ A dissenting opinion is provided (Annex III), see Chapters 3 and 4 therein.

⁴⁹ A dissenting opinion is provided (Annex III), see Chapter 6 therein.

⁵⁰ A dissenting opinion is provided (Annex III), see Chapter 5 therein.

⁵¹ A dissenting opinion is provided (Annex III), see Chapter 6 therein.

⁵² This has also been topic of debate in the Committee on Agriculture and Rural Development on October 13, 2015 (http://www.europarl.europa.eu/meetdocs/2014_2019/documents/agri/oj/1074/1074951/1074951en.pdf; topic 11), and the Luxembourg Presidency has prepared a note on "The impact of a recent decision of the European Patent office (EPO) concerning the patentability of plant traits on the plant breeders' rights regime" that was discussed in the Council (Agriculture and Fisheries) on 22 October 2015 (<http://data.consilium.europa.eu/doc/document/ST-12943-2015-INIT/en/pdf>).

Here, the fact that plants obtained by essentially biological processes may not always be distinguishable from plants obtained by technical processes is particularly relevant, as it means that the scope of patents on the latter plants may encompass plants obtained by essentially biological processes. Excluding plants obtained directly by essentially biological processes would thus only partly resolve the perceived problem: even in the scenario where these are not deemed patentable, they may fall under the scope of a patent on a plant.⁵³

This question however is not linked to patentable subject matter but rather to the scope of product patents and thus it is more an infringement issue. In the discussion it was proposed that this could be resolved by reversal of the burden of proof. Such a concept is already known in plant breeding in relation to essentially derived varieties under the plant variety system and well possible as breeders keep records of the breeding history⁵⁴. Because one breeder cannot prove how another breeder has developed a new variety, if there is *prima facie* sufficient reason to do so (e.g. a high degree of phenotypic or genotypic conformity), reversal of the burden of proof will take place and the breeder of the alleged essentially derived variety will be forced to open his breeding records. This could be applied in this scenario as well, where an alleged infringer of a patent would need to show that he obtained the plant by an essentially biological process and independent of the patented material.

However, even with the reversal of the burden of proof in place, product protection is absolute, i.e. a claim for a product covers all products falling under the scope of the claim, irrespective of the way the product was made. So even if a product obtained by an essentially biological process were in itself not patentable, if this product could be obtained using a technical process and could be patented, the scope of the product protection would also encompass the product obtained by different means.⁵⁵

Thus, what would additionally be needed to avoid that a plant obtained by an essentially biological process falls under the scope of a patent on a plant obtained by a technical process is an exclusion of the plants obtained by an essentially biological process from the scope of protection. Such exclusion of something independently developed that could fall under the scope of an existed patent would be akin to the exemption of independent creation in copyright law^{47, 56}.

It should be kept in mind that this scenario would only apply in the hypothetical case where plants obtained by essentially biological processes were not patentable. This is not the case in Europe today, as G2/12 and G2/13 emphatically state that such plants are patentable. Although the possibility of exclusion from patentability of plants obtained by EBP has been discussed, including the additional conditions that would be required, it was not agreed by the Experts that such an exclusion was desirable.

⁵³ A dissenting opinion is provided (Annex III), see Chapters 6 and 10 therein.

⁵⁴ See article 14.5 UPOV Convention 1991 and article 13.5 Regulation on plant variety rights.

⁵⁵ A dissenting opinion is provided (Annex III), see Chapter 6 therein.

⁵⁶ The burden of proving independent creation rests on the alleged infringer. This also means that authors wishing to mount such a defence need to present documentation of their creative process and preserve the evidence of evolution. Analogously, apart from keeping records of breeding, plant breeders would need to prove independent creation, i.e. creation without the intent to escape patent infringement (not breeding as a work-around).

In a study made by epi Biotech Committee in 2014, included as Annex II⁵⁷, it was shown that 2 out of 38 EPC countries exclude in their national laws from patentability plant products directly obtained by an essentially biological process. These countries are Germany and the Netherlands. It seems thus that the possible concerns regarding plant patents have not led to legislative changes in the large majority of EPC countries to date.

3.5. Conclusion and recommendations

There are three categories of recommendations the Experts could make, here indicated with the option and the number of Experts who support it:

- 1) Taking no action (11 out of 15)
- 2) Request a clarifying statement by the Commission (4 out of 15)
- 3) Recommend legislation to make clear what is unclear:
 - as separate legislation (4 out of 15, as fall-back)
 - by reopening the Directive (2 out of 15, as second fall-back).

The Experts agree that the allowability of patents on plants obtained by essentially biological processes may in some cases impinge upon the effectiveness of the exclusion of the processes from patentability.

However, a majority of eleven Experts recommends taking no action. Thus, in view of the difficulty to discriminate plants obtained by essentially biological processes from other plants, the unintended consequences legislation may have⁵⁸ (particularly in case of a complete reopening of the Biotech Directive, which would not only affect the plant breeding sector, but also the biotech industry at large and even the pharmaceutical industry), and the fact that the breeders' exemption foreseen in the Agreement on a Unified Patent Court will at least partly resolve this issue (i.e. it addresses access to plant material, not commercialization of the material – see Chapter 5), these Experts consider that measures are not warranted, as the possible consequences of the solutions are not commensurate with the size of the problem.

Four members of the Expert Group disagree with the conclusions of the EBoA. This because access to genetic resources for the purposes of further breeding is important for the breeders, they come in all cases from pre-existing natural populations, and should in these Experts' view not be blocked by patents. These members would welcome a statement from the Commission clarifying that plants obtained by essentially biological processes should not be patentable. If such clarification is not possible, these members support a solution in the form of separate legislative action. This may entail introducing a reversal of the burden of proof and limiting of scope as discussed above, and/or the introduction of a breeders' exemption.⁵⁹

However, a complete reopening of the Biotech Directive as a possible solution is only supported by two Experts, and only as a second fall-back option. In the opinion of those dissenting Experts, that is

⁵⁷ The contributions regarding the national laws have been made by epi members of the Biotech Committee and by epi Board members.

⁵⁸ Addressed in more detail in the conclusions of Chapter 5.

⁵⁹ This view is elaborated in a dissenting opinion annexed to this report as Annex IV.

still a course of action that is preferable to taking no action, and is their recommendation if it is not possible to legislate otherwise.

Chapter 4. Patents for plants v plant varieties

4.1 Introduction

The boundary between patent protection for plants and plant variety protection is by no means a new issue: basically, the introduction of Art. 53(b) in the EPC lies at the origin of it, but the debate on where the dividing line should be drawn started mainly when patents on plant-related inventions granted by the EPO gained the spotlights. Of note, this is long before the inception of the Biotech Directive⁶⁰. However, the Directive provided further legal grounds on the distinction and exclusion, and introduced a definition for plant variety into the EPC. It is noteworthy that while the Directive was under discussion, the EPO ceased granting patents on plants and animals, waiting the result of referral G1/98. After the G1/98 decision was issued (which was also after the Directive had been adopted), the EPO restarted granting patents on plants and animals.⁶¹

4.2 Legal basis

The exclusion of plant varieties from patenting is laid down in Article 4 of the Biotech Directive:

Article 4

1. The following shall not be patentable:

(a) plant and animal varieties;

(b) essentially biological processes for the production of plants or animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

This provision is incorporated in the EPC as Article 53(b) (for Art. 4(1) and (3)) and Rule 27(b) EPC (for Art. 4(2))

What is a plant variety?

The Biotech Directive, in article 2(3), refers to Art. 5(2) of Regulation 2100/94/EC on the Community Plant Variety Right, according to which

“For the purpose of this Regulation, “variety” shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

– defined by the expression of the characteristics that results from a given genotype or combination of genotypes,

⁶⁰ See e.g. T320/87 (Hybrid plants), issued 10 November 1988, on whether hybrid plants and seeds are plant varieties; and G1/98, issued 20 December 1999, relating to plant varieties as products of recombinant gene technology.

⁶¹ A dissenting opinion is provided (Annex III), see Chapter 3 therein.

– distinguished from any other plant grouping by the expression of at least one of the said characteristics, and

– considered as a unit with regard to its suitability for being propagated unchanged.”

The identical text is found in the EPC as Rule 26(4) EPC.

The EU Regulation on Community plant variety rights (hereinafter CPVR regulation) states in article 92 that cumulative protection is prohibited:

Art. 92:

1. Any variety which is the subject matter of a Community plant variety right shall not be the subject of a national plant variety right or any patent for that variety. Any rights granted contrary to the first sentence shall be ineffective.

2. Where the holder has been granted another right as referred to in paragraph 1 for the same variety prior to grant of the Community plant variety right, he shall be unable to invoke the rights conferred by such protection for the variety for as long as the Community plant variety right remains effective.

4.3 Discussion

The main argument against allowing patents for plants where the technical feasibility is not limited to a specific plant variety is that it makes the distinction between what is a patentable plant and a non-patentable plant variety obsolete.

Put in a historical perspective, whereas the EPO originally granted patents on plants and animals, this practice was temporally altered after the decision in the so-called PGS case in 1995 (T356/93). Based on this decision, it no longer granted patents on plants and animals because these patents were regarded as inevitably extending to plant and animal varieties. This was seen as a contradiction of the wording of Article 53(b) EPC.⁶²

The EPO restarted granting patents on plant-related inventions after decision G1/98 was issued in December 1999. This, it should be noted, is after the implementation of Directive 98/44/EC, which became part of the Implementation Regulations of the EPC in June 1999. These patents are based on Article 4 (2) of Directive 98/44/EC recited above.

The EBoA has explained in the G1/98 decision why it believes there is a distinction between (patentable) plants and (non-patentable) plant varieties. As the EBoA explained in the G1/98 case, the reference to the expression of the characteristics that results from a given genotype or combination of genotypes is a reference to the entire constitution of a plant or a set of genetic information. The concept of plant variety requires plant groupings to be defined by their whole genome, not merely by individual characteristics (reasons 3.8).

As the EBoA in the G1/98 case further explained, in contrast, a plant defined by single recombinant DNA sequences is not an individual plant grouping to which an entire constitution can be attributed.

⁶² A dissenting opinion is provided (Annex III), see Chapter 3 therein.

It is not a concrete living being or grouping of concrete living beings but an abstract and open definition embracing an indefinite number of individual entities defined by a part of its genotype or by a property bestowed on it by that part (reasons 3.1)

In other words, any plant grouping that does not fulfil the requirements above, would not be a plant variety. For instance, a genetically modified plant which has inserted in its genome a gene that makes the plant herbicide resistant, would not be a plant variety, as such plant grouping would not be defined by its whole genome, but by an individual characteristic, i.e. the herbicide resistance. An invention for such plants would embrace an indefinite number of individual entities defined by a part of its genotype or by a property bestowed on it by that part. Further in the words of the EBoA in the G1/98 case, such an invention aims at providing tools whereby a desired property can be bestowed on plants by inserting a gene into the genome of those plants.⁶³ It is as such not the creation of a new plant variety. There is no taxonomic category defined.⁶⁴

Is a claim to a plant variety now only excluded if it is claimed as a plant variety, or also if it is claimed as a plant, but would be applied to plant varieties? The invention is in such a hypothesis not limited to plant varieties, even though it is admitted that one of the main applications is plant varieties. But the result of the modification by genetic transformation is not necessarily a plant variety.⁶⁵ Hence, a claim for a plant in general, not limited to a specific plant variety, constitutes patentable subject matter and is not excluded from patent protection for being a claim for plant varieties.⁶⁶ A plant which has a single gene inserted into it in order to introduce a specific characteristic is defined by that single characteristic and is not a plant variety in the view of the EBoA.^{67,68}

Nevertheless, it is important to realize that usually what will be brought on the market are not plants (e.g. maize), but individual plant varieties (i.e. one or more different varieties of maize). Thus, even though patents are granted for plants and not for varieties, the product falling under the scope of the patent in practice often is a plant variety. Consequently, there is an observable overlap between what is not patentable (plant varieties) and what is patented (plants covering also plant varieties) creating a significant interface between patent law and the plant variety protection system.

Moreover, every claim to plants will embrace plant varieties, since a plant variety is a plant grouping of the lowest possible rank. When claiming a species, or even a higher rank, it will always embrace plant varieties: by way of example all Golden Delicious apples (variety) are apples (species), but not all apples are Golden Delicious.

Thus, a patent claim for a plant may cover multiple varieties.

⁶³ G1/98, point 3.8 of the reasons.

⁶⁴ G1/98, point 3.1 of the reasons.

⁶⁵ G1/98, point 3.1 of the reasons.

⁶⁶ See also Art. 4(2) biotech directive, and headnote I of G1/98: A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC, even though it may embrace plant varieties.

⁶⁷ LLEWELLYN, M., ADCOCK, M., *European Plant Intellectual Property*, Hart Publishing, Oxford, 2006, 314. See also at p. 301 where the authors state that according to ROBERTS, a plant variety is characterised by essentially all of its genes (phenotype), and not simply by one gene.

⁶⁸ Parts of this section are taken from, BOSTYN, S.J.R., *Patentability of Plants: At the Crossroads between Monopolizing Nature and Protecting Technological Innovation? The Journal of World Intellectual Property* (2013) Vol. 16, no. 3–4, p. 108. with the author's kind permission.

It is possible to claim a plant grouping which is defined by one characteristic rather than by its whole genome or group of characteristics. Following this reasoning, the plant grouping does not consist of a specific taxonomic unit of plants, but it may consist of a taxonomically non-specific plant grouping, which can lead to the development of a great number of plant varieties, but which in se cannot be confined to a certain specific taxonomic unit, and certainly not to a specific plant variety.

In summary, although the reasoning provided in G1/98 is useful as a legal construct to distinguish between plants and varieties, scientifically, the boundary is a lot less sharply defined. For techniques that specifically introduce or alter one gene, the case law is clear. Regarding the use of breeding techniques consisting of crossing, selection and identification of the more promising elements through markers, this might raise new problems which were not present when assessing patent applications related to genetically engineered plants.⁶⁹

One of the main issues why the boundary between patent protection for plants and plant variety protection is contested relates to access to biological material. The plant variety right system contains a full breeders' exemption (see chapter 5), which is not incorporated (or not incorporated to the same extent) in patent law, a limited form of such exemption allows breeders to use the protected material for further breeding without permission of the rights holder. Without and outside of such an exemption a license is needed to use patented inventions concerning plants.

Although plants have been patentable for some time (and, given decisions G2/12 and G2/13, this includes plants obtained by essentially biological processes), the patenting activity in this field has increased in the last years in parallel with technical development (cf. Fig. 2.2) and one patent may cover a lot of different varieties. So although patent protection is available, breeders might not have fully realized that 'conventional', non-GM, plants (i.e. wherein introduction of a trait relies on crossing of whole genomes) could be patented, as they typically relied on the PVR system and the Biotech Directive seemed in their view to refer to GMOs⁷⁰. Breeders are now confronted with the fact that biological material may be patent protected and is no longer freely available for further breeding.

As made clear in G1/98, the extent of exclusion from patentability should correspond to the availability of plant variety protection. Thus, the balance between the two systems should ensure that the interface does not conflict with the original intents of the legislators both as regards patent law and plant variety rights. Where an interface does exist between the two systems for legitimate reasons, pragmatic solutions need to be found (e.g. ensuring the availability of plant genetic material

⁶⁹ A dissenting opinion is provided (Annex III), see Chapter 4 therein.

⁷⁰ This interpretation is based solely on recitals 52 and 53 in the preamble of the biotech directive. These recitals only discuss the compulsory cross-license in the field of exploitation of new plant characteristics resulting from genetic engineering:

"(52) Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where, in relation to the genus or species concerned, the plant variety represents significant technical progress of considerable economic interest compared to the invention claimed in the patent;

(53) Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where the invention represents significant technical progress of considerable economic interest"

for further breeding) while finding the right balance between the interests of the various stakeholders. This will be further discussed in the section on the breeders' exemption.⁷¹

4.4 Conclusion and recommendations

The majority of the Expert Group saw no change of the situation in the light of recent technological developments, as these developments have not caused a paradigm shift in this particular area. With regard to recommendations, the options and the number of Experts who support them are as follows:

- 1) Taking no action (11 out of 15)
- 2) Request a clarifying statement by the Commission (4 out of 15)
- 3) Recommend legislation to make clear what is unclear:
 - as separate legislation (2 out of 15, as first fall-back)
 - by reopening the Directive (2 out of 15, as second fall-back).

Although some members of the Expert Group were of the view that the exclusion of plant varieties from patentability and the consequences of decision G1/98 cause an internal contradiction within the patent system for plant-related inventions, the majority of the Expert Group saw no reason for a change in law. Consequently, the majority of the Experts (11 members) recommend that no action is taken to address this point.

However, four Experts took the view that clarifications at least are needed to better distinguish between patents concerning plants and plant variety rights. These Experts would like a clarifying interpretation on the exclusion of plants obtained by essentially biological processes from patentability (in contrast to the EPO's conclusion in G2/12) (see chapter 3), as this would in their view be a desirable step towards diminishing the interface between the two IP rights. They thus recommend the Commission to issue such a clarifying statement.

Two of these four Experts further expressed the need for a legislative change in case such a statement cannot be made, to exclude plant varieties from the scope of protection of patents relating to plants. This is preferable as separate legislation (the first fall-back option); if this is not feasible, reopening the Biotech Directive is envisaged as second fall-back option for those two Experts.

⁷¹ A dissenting opinion is provided (Annex III), see Chapter 4 therein.

Chapter 5. Breeders' exemption

5.1 Introduction

The concept of breeders' exemption as laid down in legislative instruments stems originally from the *sui generis* plant variety right protection systems. Prototypical representative is the UPOV Convention.

The UPOV plant variety rights system is a *sui generis* IP system, which has been specifically conceived to provide IP protection for plant varieties as such taking into account all the specificities of the breeding sector. One such key specificity is that plant breeding is based on the existing available gene pool and achieves its goals by recombining those with the view of creating something new and innovative. Thereby, plant breeders continuously improve on each other's material which has been translated in the UPOV-system in its 'breeders' exemption' allowing for the free use of protected varieties for further breeding and for the commercialization of the newly bred variety.⁷²

The concept of a breeders' exemption was until recently not present in the patent system. Neither the EPC nor the Biotech directive provide for such a breeders' exemption. That absence has led to concerns about the freedom to operate and reduced availability of plant genetic material for further breeding. Indeed, breeders now need to take into account patent protection (rather than being able to use material without having to worry about IP protection). The free access to material that the sector was used to has fundamentally changed. Some are of the opinion that breeders need to adapt to the situation, others think this puts too much strain on breeders.

When discussing the breeders' exemption, we should be careful to distinguish two types:

- The 'full breeders' exemption', which enables anyone to use the protected material, without permission of the right holder(s), for the purpose of breeding, or discovering and developing other plant varieties and extends to commercial exploitation. This breeders' exemption is the form present in the UPOV Convention and the Community Plant Variety Right system (see footnote 65)
- The so-called 'limited breeders' exemption', which is an exemption that enables anyone to use the protected material, without permission of the right holder(s), for the purpose of breeding, or discovering and developing other plant varieties. This limited breeders' exemption does not extend to commercial exploitation of the thus obtained plant varieties. In case of commercialization, the breeders of those newly developed varieties have to request the right holder (typically a patent holder) for a licence on the genetic material if the protected material or subject matter is still present in the plant variety that is to be commercialized.

⁷² See Art.15(1)(iii) UPOV 1991: "The breeder's right shall not extend to [...] (iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to Article 14(4) in respect of such other varieties."

For the Community Plant Variety Right, see Art. 15 CPVR 2100/94/EC: "(c) acts done for the purpose of breeding, or discovering and developing other varieties; (d) acts referred to in Article 13 (2) to (4), in respect of such other varieties, except where the provisions of Article 13 (5) apply, or where the other variety or the material of this variety comes under the protection of a property right which does not contain a comparable provision."

Importantly, the breeders' exemption only relates to the use of biological material. For the use of patented techniques or tools to obtain the biological material, permission of the patent holder is required.

5.2 Discussion

The Expert group acknowledged the existence of the two abovementioned types of breeders' exemption.

Unless explicitly mentioned otherwise, the present discussion is confined to the limited breeders' exemption as introduced in patent legislation, creating an exemption to patent infringement for the use of patented material in breeding activities. In all countries where a breeders' exemption has been introduced in national patent laws (see further below), the limited version has been introduced. Several members of the Expert Group also questioned whether a full breeders' exemption, i.e. including an exemption against patent infringement for commercialisation, would be in accordance with fundamental underlying principles of patent law to provide effective patent protection against any commercial activity infringing the patent right.

Although the argument can be made as to why introduction of a breeders' exemption would benefit plant breeding (cf. *supra*), the question remains what the effect on scope of patent protection is.

An evaluation of the reasons for introducing a breeders' exemption or not requires a multi-faceted approach.

One of the most claimed and objectively speaking appealing rationales for introducing a breeders' exemption in the patent system is that such an exemption would guarantee access to genetic material with a view to develop new varieties. The access to genetic material for breeding is important for quick innovation in plant breeding. In the absence of the availability of a breeders' exemption, the argument goes, all this material is locked up in patents and not accessible to third parties without obtaining a licence, which in turn will go at the expense of further technological development and in the long run a loss of biodiversity.⁷³ In the same vein, the argument concludes that this would in the end also be beneficial to farmers, growers and consumers, as it would lead to a higher diversity of varieties on the market⁷⁴.

The obvious argument against introducing a breeders' exemption in patent law, even if it is a limited version, is that it hollows out patent protection for patent holders. Whilst in all other areas of technology, patent holders would be able to object to the use of patented subject matter for the commercial development of new products, under a limited breeders' exemption such would no longer be possible. Under the present patent system of all EU Member States, the only exemption one can avail oneself of is the research exemption, according to which research ON the patented

⁷³ See, Sven J.R. Bostyn, *Patentability of plants: at the crossroads between monopolising nature and protection technological innovation?* The Journal of World Intellectual Property (2013) Vol. 16, no. 3–4, p. 132.

⁷⁴ While this logic is *prima facie* appealing, it should be remarked that this claim is hard to substantiate, as there currently is no EU-wide breeders' exemption for patents. Moreover, the number of plant varieties registered yearly has not decreased in recent years (see section 1.3), so the existence of patents on plant-related inventions has no, or a not yet visible, negative effect on plant variety registration.

subject matter for RESEARCH PURPOSES is allowed.⁷⁵ In most Member States, this exception has been interpreted quite narrowly and it would never include the kind of activities allowed under a limited breeders' exemption.

Irrespective of whether one is a proponent or opponent of introducing a limited breeders' exemption into the patent system, a number of considerations need to be made before a final conclusion can be drawn.

As we have seen, the limited breeders' exemption as it is now known in statutory materials is inspired by a quite different legal regime, i.e. the plant variety right system. It is not always recommended to make a legal transplant from one regime to another.⁷⁶ Each system and its sector (especially plant breeding) has its own rationales and characteristics. The argument against this line of reasoning warning for legal transplants would obviously be that in today's technological environment, there is at least to some extent overlap between the two worlds and that the patent system undermines a key feature of the plant variety right system, i.e. the breeders' exemption.

The breeders' exemption is regarded by breeders as a prerequisite for further innovation in plant breeding. New varieties are based on the use of biological material such as plants and cannot be developed out of information on paper. It is also important to note that whether a variety is protected by PVR or a patent or not, the breeder has always a lead in the market: it is not just a matter of breeding the variety, but also of producing seeds and testing varieties which process takes several years – thus the original breeder is not immediately threatened by other breeders using his variety in a breeding process. This lead period is getting shorter due to technical advances in breeding.

In favour of the introduction of a breeders' exemption in patent law, it is sometimes argued that never before has the patent system overlapped to such an extent with the work of breeders. Technological developments outside of the area of transgenic plants are being increasingly used by breeders to develop new varieties. That is a new development, and might in the absence of a breeders' exemption affect breeders in their businesses more than was the case in a situation where only transgenic plants were being made by genetic engineering methods. As access to biological material is essential for further innovation in breeding, a model without a breeders' exemption might hamper their viability and innovative capabilities.

However, several Experts pointed out that the patenting of plant-related inventions does not necessarily mean that these are not accessible anymore: it means that a license is needed. For breeding methods, reference was made to the Ogura case. Ogura is a patented hybridisation technology developed by the French public research institute INRA that is used to make Oilseed Rape (OSR) hybrids with higher yields. The first hybrid seeds based on the Ogura innovation were

⁷⁵ Notable exception is Belgium, which equally allows research WITH the patented subject matter, see Art. XI.34. § 1(b) Wetboek Economisch Recht/Code de droit économique (Code of Economic Law): “De uit een octrooi voortvloeiende rechten strekken zich niet uit tot : [...]; b) handelingen die op en/of met het voorwerp van de geïntroëeerdte uitvinding worden verricht, voor wetenschappelijke doeleinden.”, “Les droits conférés par le brevet ne s'étendent pas: [...]; b) aux actes accomplis à des fins scientifiques sur et/ou avec l'objet de l'invention brevetée.”

⁷⁶ Bostyn, 2013, *loc.cit.*, 132.

introduced in 2000 and resulted in rapid adoption by farmers over the last decade⁷⁷. This technology is available on the market through non-exclusive licenses to several seed companies. A recent study analysing the socio-economic effects⁷⁸ found that about 80% of the total economic benefit accrues to farmers and further downstream towards processors and end consumers, while it took INRA and seed companies approximately 15 years to recover their R&D investments. Since the expiry of the first patent, the take-up in the industry of the previously patented technology has quickly sped up. This case illustrates that patented technology in the field of plant breeding does not necessarily put a brake on innovation, neither is it necessarily detrimental to stakeholders, including seed companies and consumers. While the patents related to technology, and not to plants per se, it is noteworthy that licenses were needed to market plant varieties created using the technology, and this did not stop breeders. However, it was remarked that universities are typically more inclined to grant a license than most companies, as it is part of their mission to translate university research to a product. There are no similar data on licenses granted by companies. Furthermore, even in the Ogura case, the rate of adoption increased after patent expiry.

Several Experts questioned as well if the increased interface between patents and PVR justify a limitation to the exclusive rights of the patent holder? One should be careful with introducing exceptions, and only if there are very solid reasons to do so: introducing a piece meal exception for a particular sector of industry could open the door for creating further and/or other exceptions in other sectors of industry, which may in the end hollow out patent protection and limit rather than foster innovation. In any case, a limitation to the exclusive rights in the area of plant breeding would be against the interest of those which base their business on legal activities around patents or those who hold patents in this area. The interest of these particular groups have to be weighed against the interests of breeders and to some extent also to the interests of a broader public such as farmers and consumers.⁷⁹

A key difference between both systems is that the PVR system protects a certain commercial variety (i.e. a product at the end of the development chain), and not an abstract technology such as is the case with the patent system. The decision for implementation of a breeders' exemption in the PVR system did not have a devastating effect on PVR right holders, as there was a considerable lead time advantage given to the PVR right holder.⁸⁰ Under the "traditional" PVR system, it also took many years before a competing breeder would be able to come on the market with a new variety developed on the basis of the protected variety by invoking the breeders' exemption.⁸¹ This lead time advantage present in the PVR system is not available in the patent system, as patents protect a technology as such, and not only a specific commercial embodiment. This has as a consequence that, if a breeders' exemption were to be introduced in the patent system, once the patent application

⁷⁷ The adoption level of Ogura hybrids by farmers reached 83% in 2012.

⁷⁸ "Who Benefits from IP Rights for Agricultural Innovation: The Case of Ogura Oilseed Rape in France" by Steward Redqueen (November 2014); commissioned by CropLife International and EuropaBio.

⁷⁹ A dissenting opinion is provided (Annex III), see Chapter 10 therein.

⁸⁰ The PVR system is subject to a considerable number of very time consuming field trials, de facto giving the right holder a lead time advantage, as a third party breeder would have to go through a similar time consuming exercise before he could ever bring his new variety on the market. Furthermore, the PVR system protects the commercial variety, and competitors would have to start analysing and "reverse engineering" the protected variety once it has entered the market, hence the lead time advantage.

⁸¹ In recent years, due to molecular breeding tools, the development time of a variety has been reduced by 2-3 years (see section 1.2). The total breeding process still is quite long however (see Figure 1.1).

has been published (which is in principle 18 months after filing date), competitors can start using the technology with a view to make their own innovations, which may be many years before any commercial embodiment is brought on the market by the patent holder. This is particularly true in the plant breeding field, where field trials and regulatory processes to be complied with take much longer than the 18 month period between filing and publication of a patent application.

Since the PVR system protects a final product and the PVR is obtained once the final commercial variety is virtually ready for marketing, a commercial product will be capable of entering the market relatively soon after obtaining the PVR (taking into account regulatory requirements which may cause further delays for all breeders alike). That is very different from patent protection, which protects a technology and is as such more remotely linked to a commercial product. Allowing third parties to freely use the patented technology for breeding purposes makes those third parties direct competitors to the patent holder who might not have a product on the market for years after the patent application has been filed. In such scenario, it is theoretically possible that both patent applicant and competitor, the latter using the patented material under a breeders' exemption, would come on the market with a commercial product at the same time, something which is inconceivable under the PVR system, for the reasons mentioned above. That implies that introducing a breeders' exemption immediately interferes with patent protection at its heart, while this is not the case for PVR systems. Or put in other words, the breeders' exemption has been devised with the specificities of the PVR system in mind, and has not been devised for other intellectual property rights.

There is one important caveat to be made in the above reasoning that supports the position that plant breeding is a special case: new varieties are not created from nothing, but are always based on existing, related material, which is not necessarily the case in other sectors. While the publication of the patent application gives the breeders access to paper information, breeding starts from actual plant genetic material. As long as they have no access to this material, plant breeders cannot use this in a breeding process. The breeders' exemption in PVR takes this particularity into account, and as the PVR protects a variety that has been bred, the material thus is actually available.

However, the interface between the two systems of protection results in the breeders' exemption losing its meaning for varieties falling under the scope of a patent because of the absence of such exemption in a patent system. Introduction of a limited breeders' exemption does not cover commercialisation, for which the consent of the patent holder will be required. Thus, it can be argued that such introduction does not completely hollow out patent protection. While this is a valid argument, it cannot be excluded that a breeders' exemption could possibly lead to circumvention of IP rights by using the patented plant to breed out where possible what is protected by a patent, whilst at the same time attempting to maintain the interesting "commercial" features of a plant variety. The idea is not to accuse breeders of possibly acting in bad faith (the goal of breeding after all is making new, improved varieties using the best material, not to alter the best material), but merely to point out that even introducing a limited breeders' exemption has consequences for patent holders as they cannot stop parallel development.

In conclusion, where does this bring us in terms of the desirability of having a breeders' exemption? In view of the above arguments, it will not be surprising to see that no unequivocally united answer has been provided to that question by the Expert Group. Based on some of the above arguments,

some members considered at least a limited breeders' exemption to be an almost natural state of affairs, whilst others had doubts about the feasibility of introducing such exception, also in view of the potential consequences for the integrity of the patent system and issues with the use of legal transplants in this area.

The Expert Group acknowledged, however, a number of statutory developments in this regard. A number of EU Member States have already introduced a limited breeders' exemption in the patent system (for a non-exhaustive overview, see Annex I to this Report). This seems to show that at least the legislature of some countries deemed the introduction of a limited breeders' exemption necessary.

Furthermore, a limited breeders' exemption has also been introduced into the future European Patent with Unitary Effect.⁸² Article 27(c) of the Agreement on a Unified Patent Court (UPC) states: "[The rights conferred by a patent shall not extend to any of the following: ...] (c) the use of biological material for the purpose of breeding, or discovering and developing other plant varieties." Some Experts suggested that the introduction of a limited breeders' exemption in patent laws at both the national level and in the UPC Agreement mitigates at least partly the potential negative consequences. It has been argued in the Expert Group that the fact that such limited breeders' exemption has been introduced into the future European Patent with Unitary Effect system does not as such cover all patents granted in the EU. With a view to achieve a deep harmonisation on this issue, a Directive to that effect or an amendment of the Biotech Directive would be required.

5.3. Conclusion

The Expert Group could not come to a consensus on the issue of the limited breeders' exemption. That lack of consensus was not only present regarding the question whether a limited breeders' exemption is a desirable legislative instrument to achieve certain goals described earlier in this Report (indeed, several members are against the notion of a breeders' exemption as such, as it introduces exemptions to patent law for one specific sector only). Consensus was also lacking on the question of, even if one would agree with the introduction of a breeders' exemption, whether that should be left to the EU Member States, or whether there should be a legislative initiative at the EU level. To start with the last issue, what is currently noticeable is that a number of EU Member States have already taken action. The trend that seems to materialise is that all countries having currently introduced a breeders' exemption, have gone for the limited version.⁸³ Question is now whether the need for harmonisation within the EU calls for a legislative intervention of the EU. The answer to that question is difficult to give, as not only is it linked to the first question, i.e. whether it is desirable to have a breeders' exemption, but also to the issue of how to organise such harmonisation activity.

One option would be to introduce a breeders' exemption into the Biotech directive, which is technically possible by introducing an amendment to the Biotech Directive. This option has, according to some members, a number of risks attached to it: at the political level, a more wholesale revision of the Biotech Directive might ensue, and these members would see this as a particularly undesirable consequence. Revision of the Biotech Directive could easily lead to requests for a

⁸² AGREEMENT on a Unified Patent Court(2013/C 175/01), OJ, C 175/1, 20 Jun 2013.

⁸³ A dissenting opinion is provided (Annex III), see Chapter 9 therein.

substantial redrafting of the Biotech Directive and a very lengthy legislative process. That would leave Europe for a long period of time in a state of legal uncertainty. Importantly, the Biotech Directive not only affects the breeders' sector, but also the biotech industry at large and even the pharmaceutical industry, so revision of the directive may have consequences for a lot more stakeholders than intended. The large majority of the Expert Group is of the belief that such a process would not be conducive to economic developments of the European life sciences sector.

Another option is to introduce it as a separate legislative initiative, not directly linked to the Biotech Directive and hence not constituting an amendment to the Directive. This is de facto already done in the Agreement on a unitary patent court (UPC), albeit that this Agreement does not cover all situations in which the Biotech Directive is relevant (see below).

A third option is also not to introduce a legislative change, and leave it to the Member States to legislate. Even though it is true that the introduction of the limited breeders' exemption into the European Patent with Unitary Effect (UP) does as such not cover patents which fall outside this category, such patents would, when looking at current practice, likely be limited in number. All European patents for which the applicant opts at grant for a UP fall in this category. All granted European patents (bundle patents) also fall under the legal frame of the Agreement on the Unified Patent Court (UPC)⁸⁴. Therefore, factually nearly all patents are covered by the breeders' exemption of the UPC as soon as it comes into force.

However, for national patents the legislation at national level is still relevant – these patents are governed by the Biotech directive, but not by the UP. Moreover, Spain, an important country for breeding, and Croatia at this moment do not participate in either the UPC or the unitary patent, so are not bound by this breeders' exemption.

Regardless of changes to the Biotech Directive, it seems likely that most EU Member States will adopt similar provisions into their patent statutes, which would lead to a de facto harmonisation, thus avoiding any of the risks attached to introducing a legislative initiative.

It is acknowledged by the Expert Group that the aim of the biotech directive is to harmonise patent law. However, to have the same legal cases governed under two laws (*in casu* the Biotech Directive and the Agreement on the Unified Patent Court) seems undesirable. Either the law in both statutes is identical (in which case it is not necessary if the Agreement on the Unified Patent Court would

⁸⁴ See Art. 3 (c) a,d (d) of Agreement on UPC. Note that the "opt-out" clause of Art. 83 covers opt out of the court, not of the UPC agreement. However, the Preparatory Committee (PC) of the UPC Agreement addressed the question of whether, when a European patent is opted out, a national court should apply national law or the UPCA provisions and in particular chapter 5 which deals with substantive provisions (including the breeders' exemption). In an interpretative note issued on 29 January 2014, the PC took the view that *"if an application for a European patent, a European patent or a Supplementary Protection Certificate that has been issued for a product protected by a European Patent is opted out (or during the transitional period the case is brought before a national court), the Agreement no longer applies to the application for a European patent, the European patent or the Supplementary Protection Certificate concerned. As a consequence the competent national court would have to apply the applicable national law."* (see <http://www.unified-patent-court.org/news/71-interpretative-note-consequences-of-the-application-of-article-83-upca> ; last accessed October 17, 2015).

This note of course only reflects the understanding of the PC and will not be binding neither for the Unified Patent Court nor for the EUCJ, which could in case of referral by a national Court decide otherwise.

apply in all EU Member States), or it is (slightly) different. In that case, it causes legal uncertainty, which everyone wants to avoid. This argues according to most Experts against modification of the Biotech Directive when the issue can be seen as resolved by the UPC.

Nevertheless, several Experts are of the opinion that legal certainty should be ensured as of now. Although the large majority of the Expert Group is of the opinion that implementation of the UPC will in practice resolve virtually all cases, implementation of the UPC may take years, and may even not happen at all. Therefore, a plea was made for the introduction of a limited breeders' exemption across Member States in the event the UPC will not be implemented – either by legislation at the national level or EU-wide.

A further argument was that, regardless of the UPC, measures should be taken to introduce a breeders' exemption in the patent system. One option to do this is the introduction of a EU-wide limited breeders' exemption. This would need legislative action, as the Agreement on the UPC does not bind all Member States and is not yet into force. However, this does not necessarily mean re-opening of the Directive. If it can be done by other legislative tools, that would be considered adequate by those supporting the introduction of such exemption.⁸⁵

Finally, the most radical view that was expressed is the abolishing of patents that cover plant varieties, and if this is not feasible, implementation of a full breeders' exemption, rather than a limited one, in the law (preferably the biotech directive). This view was expressed by one expert, while one other expert proposed the reverse order, i.e. implementation of a full breeders' exemption, and if this is not feasible, the abolishing of patents that cover plant varieties. The reason to prefer the full breeders' exemption is because this is also the form that is present in the PVR system. It has to be noted that the introduction of a full breeders' exemption in patent law practically equals a royalty-free license of right. If neither the abolishing of patentability nor the introduction of a full breeders' exemption is feasible, introduction of an EU-wide limited breeders' exemption would be the most preferred option for the Experts expressing this opinion.

Recommendations

The different options and the number of Experts who support them are as follows:

- 1) Taking no action (9 out of 15; of which 6 explicitly oppose a breeders' exemption)
- 2) Request a clarifying statement by the Commission (0 out of 15)⁸⁶
- 3) Recommend legislation to make clear what is unclear:
 - as separate legislation (6 out of 15)
 - by reopening the Directive (2 out of 15, as fall-back).

A majority of 9 Experts recommend that no action is taken. They justify this by referring to the perceived risk of reopening the Biotech Directive and pointing out that the Agreement on the UPC will in practice seem to solve the large majority of cases. Six of the nine Experts additionally are

⁸⁵ A dissenting opinion elaborating this point of view is annexed to this report as Annex IV. This opinion is supported by three other members of the group.

⁸⁶ In the absence of any legal basis for a breeders' exemption in the directive, a clarifying statement was not considered applicable here.

against a breeders' exemption as such⁸⁷, the other three Experts recommending no action are neither for nor against a breeders' exemption.

Six Experts argued for legislative action, but to differing degrees. Four of them support the introduction of a EU-wide limited breeders' exemption through separate legislation (i.e. without amendment of the Biotech Directive). Three of these four have indicated that the implementation of the UPC could have resolved the issue for them, but as it is unsure whether all EU Member States will implement a breeders' exemption into national law in a timely fashion, they join the argument for providing some form of limited breeders' exemption across Member States as soon as possible.⁷⁸

The last two Experts calling for legislative action prefer the implementation of a full breeders' exemption (or the equivalent introduction of a license of right) with the abolition of patents that cover plant varieties as a fall-back, or vice versa, as discussed above. This may be as separate legislation (their preferred recommendation), but also by amendment of the Biotech Directive (the fall-back recommendation for these two Experts).

⁸⁷ One Expert has written a dissenting opinion expressing the reasons for opposing the introduction of a breeders' exemption, annexed to this report as Annex V. This opinion is supported by the five other members that are principally against a breeders' exemption.

Chapter 6. Compulsory cross licensing

6.1. Introduction and legal provisions

With regard to compulsory cross-licensing, the relevant provision is Art. 12 Directive 98/44/EC, which says:

“1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:

(a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;

(b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

4. Each Member State shall designate the authority or authorities responsible for granting the licence. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply.”

Compulsory licensing and cross licensing are as such not new phenomena. Most Member States of the EU already contain a statutory framework for such licenses.

What is particular about the present system is that it concerns a cross licensing system between two different intellectual property/*sui generis* regimes, instead of the more traditional licensing system within one intellectual property regime. As will become clear in what follows, this particularity is not without its importance in the evaluation of the regime introduced in the Biotech Directive.

6.2. Discussion

The Expert Group acknowledged that the wording of Art. 12 of the Biotech is not always very easy to understand, and to the extent that it can be understood, various concepts in the provision were not necessarily straightforward to be put in practice.

Article 12 legislated for two different situations, i.e. where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent on the one hand, and the situation where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right.

For purposes of the discussion, only the first situation seems to be relevant. The reverse situation, i.e. where a patent holder cannot exploit it without infringing a prior plant variety right would in most cases not be problematic, as the patent holder could avail himself of the breeders' exemption existing under the plant variety right system.⁸⁸

A first difficulty was identified in the use of the wording "acquiring" or "exploiting" a plant variety right. The Biotech Directive requires that a compulsory cross license can only be obtained by a breeder if he could not acquire or exploit a plant variety right without infringing a patent. The term "acquiring" is particularly vague. Does this term assume that the breeding has already taken place, and the breeder is now in the phase of applying for a plant variety right? Or does the term "acquiring" include all activities preceding the effective filing for the plant variety right? If the first interpretation would be followed, that would imply that the breeder might have already spent considerable time and money in the breeding process, and if no license would be obtained, all that activity would be "wasted", as the new variety could not be used (and thus the variety right could not be exploited) without infringing a patent. That is potentially creating considerable uncertainty. If the second interpretation of the term "acquiring" would be followed, then a license could be obtained at an early stage of the breeding process, i.e. long in advance of the actual filing for the plant variety right. But that license, which is subject to payment of a reasonable royalty, could later appear to be without use, as the use of the patent protected material may never result in a plant variety in the end. Once again, resources are "wasted". Thus, regardless of the interpretation of "acquiring", this provision creates uncertainty for the breeder. Further, a practical inconsistency in this second interpretation is that it is not possible to prove that a variety constitutes a significant technical progress of considerable economic interest compared with the invention, as long as there are no varieties developed yet. It is worth remarking that this type of situation might look not that different from the situation of an inventor/applicant developing a new microorganism strain. It may also take years to develop a production strain, which may infringe (an) earlier patent(s). The money is wasted, if a license is not obtained. However, in the case of micro-organisms (and also in other fields), the interplay is between two patents, which need to fulfil the same criteria and have the same exemptions. For plant variety right, there is an interplay between two different legal systems, and both the requirements and the exemptions in both systems differ.

A second layer of issues was identified in Art. 12(3) of the Biotech Directive, which lays down conditions under which a compulsory cross license can be obtained. Indeed, the obtaining of a compulsory cross license is only possible provided the applicant is able to demonstrate that (a) he/she has applied unsuccessfully to the holder of the patent (or of the plant variety right) to obtain a contractual licence; and (b) the plant variety (or the invention) constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

Both (a) and (b) were by some Expert Group members seen to raise issues. Under requirement (a) it is expected that ancillary negotiations to arrive at a contractual license have been unsuccessful. Even

⁸⁸ Theoretically, a possible exception could be a patent holder that wants to market an essentially derived variety, as the breeders' exemption does not apply to those. However, a patent may not be limited to a variety, and an essentially derived variety is very unlikely to meet the criteria of 'significant technical progress of considerable economic interest compared with the protected plant variety', so this seems only a hypothetical scenario.

though this is quite a standard requirement in compulsory licensing regimes, some members of the Expert Group were of the view that this creates legal uncertainty, as it is very difficult to evaluate when a reasonable offer for a license has been made and refused. This is a matter that has been the subject of case law of the CJEU relating to competition law, but it is difficult to derive from that case law very clear guidance. As this is a complicated issue that is clearly outside of remit of the Expert Group, the issue was not further discussed. Other members emphasised that the requirement introduced here is not an exceptional regime, and indeed, as mentioned earlier, very common in compulsory licensing schemes in the Member States.

Regarding requirement (b), it was held by some members of the Expert Group that it is very difficult if indeed possible at the time of applying for such license to demonstrate that the plant variety constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent. That will even more be the case if the license is applied for prior to acquiring the plant variety right, at which time it will be very difficult indeed to prove that the plant variety which has not even been obtained constitutes that significant technical progress of considerable economic interest. In this regard, it should be noted that plant variety protection is different from patent protection in that plant varieties are granted for varieties that are new and that are distinct, uniform and stable – the so-called DUS criteria. In other words, a technical aspect or inventive contribution is not required to obtain a plant variety right, in contrast to patents for inventions. Bearing in mind the DUS criteria, it can easily be seen that ‘significant technical progress’ is hard to demonstrate for a plant variety, as technical progress is not a prerequisite for varieties in the first place. In addition, as the terms ‘significant’ and ‘considerable’ are not clearly defined, application of the condition is likely to give rise to interpretation problems to the extent that it does not provide the legal certainty the potential users of this system would desire.

All of the issues above would not be conducive to filing for such licenses, and the question was being asked within the Expert Group whether the regime could ever be practically applied. Furthermore, those members who were of the belief that the regime as it has been worked out in Art. 12 could not function effectively for plant breeders also argued that, in view of the non-effectivity of the system, the existence of it should not be used as an argument for those who would profess the view that more expansive access to patented material by breeders should not be considered as there is a regime providing such access.

As already mentioned earlier, the conditions laid down in Art. 12 Biotech Directive are as such nothing out of the ordinary, and are in fact already for some time part and parcel of national compulsory licensing systems. And even at the international level, the concepts are well known. In fact, Article 12 Biotech Directive seems to have been directly inspired by Art. 31(I) of the TRIPs Agreement, which states:

“Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use⁸⁹ of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

⁸⁹ “Other use” refers to use other than that allowed under Article 30 TRIPs Agreement.

[...]

(l) where such use is authorized to permit the exploitation of a patent (“the second patent”) which cannot be exploited without infringing another patent (“the first patent”), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.”

There is hence a basis for introducing a similar system in the Biotech Directive. Objection against such a line of reasoning can be built upon the argument that, whilst Art. 31(l) TRIPs Agreement organises a compulsory cross licensing system within the patent system, Art. 12 Biotech Directive introduces a system which combines two quite different intellectual property/*sui generis* regimes. That combination, which creates its own problems and idiosyncrasies, as discussed above, is in the view of some members of the Expert Group bound not to function properly.

It was argued in the Expert Group that plants constitute a specific field, as evidenced by TRIPs having a specific provision that allows exclusion of patentability of plants and plant varieties (Art. 27.3.(b)). However, this view is not supported by the majority of the Group, and Art. 31 of TRIPs does not make a distinction for plant-related inventions.

To the Experts’ knowledge, no case is known where such compulsory cross license has been given, nor is it clear whether a compulsory license has ever been requested. There simply are no data available in public records.

Whether the system as provided in Art. 12 is capable of functioning properly or not is not something the Expert Group could agree upon, for the reasons mentioned above. Nevertheless, it seems that the bar is indeed quite high before one can apply for such license. An ancillary question is whether breeders in fact suffer from the regime, in view of some impractical conditions. As with most compulsory licensing systems, they are rarely used, hence it is not surprising to find that there is no hard evidence to that effect.

But a recent initiative of the International Licensing Platform Vegetable (ILP Vegetable) shows that at least the breeding sector is interested in non-exclusive licensing. This may illustrate the need within the industry to have access to biological material for further innovation in plant breeding. Under the scheme, eleven companies, which comprise both listed companies and family businesses from Switzerland, Germany, Japan, France and the Netherlands, have worked together to establish the ILP Vegetable with an aim to provide plant breeders around the world with faster, more efficient and cost effective, guaranteed access to crucial plant breeding traits that are currently covered by patent claims by ILP Vegetable member companies.⁹⁰ Reservations were made in the Expert Group as one

⁹⁰ See <http://ilp-vegetable.org/>, last visited on 31 August 2015.

major breeding company has decided not to join up to now. However, this might still be under consideration. In addition, not joining the system does not automatically imply that a company does not grant licenses.⁹¹

The exact and underlying motivations to set up the ILP Vegetable have been communicated as: not to await the outcome of the political and public debate but to create a system that improves access to biological material that is covered by patents. Since this is a very recent initiative, it is much too early to draw any conclusions as to the practical implications and functioning of the system.

6.3. Conclusion

The Expert Group acknowledged that the wording of Art. 12 of the Biotech Directive regarding compulsory cross licensing is convoluted and in the view of most members not very useful. The legal transplant which had been carried from a regime within the patent system to a system of combined patent and plant variety rights systems, with each its own rationales and provisions, make the system in the view of some members of the Expert Group deficient, also related to the fact that the wording used in Art. 12 uses a patent law logic and vocabulary.

The subsequent question was then to evaluate whether there was a need to amend the provision of the Biotech Directive to make it more effective. Ideally, the Expert Group would then suggest an appropriate wording.

The Expert Group has not been able to arrive at a common wording, also and in particular in view of the fact that there was no agreement as to whether an amendment of the provision would have to be recommended. Changing the wording of Art. 12 would require an amendment of the Biotech Directive. This option has, however, a number of risks attached to it, as at the political level, a more wholesale revision of the Biotech Directive might ensue, and at least some members of the Expert Group would see this as a particularly undesirable consequence.

Secondly, questions were also asked whether the issues identified merit an amendment in the first place. As said earlier, a large majority of the issues relate to wording which is already present in national and international statutory instruments, and the Expert Group has not been able to identify examples of overwhelming debate to amend the provisions of those statutory instruments. No evidence has been presented which would show that breeders are particularly prejudiced under the present regime. Some members referred in this connection to condition (b) of Art. 12(3) and stated that as this condition would in practice never be fulfilled in view of the different nature of both regimes of protection, plant variety right holders would in effect be barred from invoking the regime of Art. 12. Others pointed out that there is in practice little difference with other compulsory licensing systems that are also not used and see no reason to make an exception for plant breeders.

Recommendations

The different options and the number of Experts who support them are as follows:

- 1) Taking no action (13 out of 15)
- 2) Request a clarifying statement by the Commission (2 out of 15)

⁹¹ A dissenting opinion is provided (Annex III), see Chapter 10 therein.

- 3) Recommend legislation to make clear what is unclear:
- as separate legislation (2 out of 15, as a first fall-back)
 - by reopening the Directive (2 out of 15, as a second fall-back).

In conclusion, despite the fact that all Experts agreed that the wording of Art. 12 is not practicable, an overwhelming majority (all members but two) of the Expert Group recommend that no action is taken. The reason for this point of view is that the possible alternatives are not commensurate with the size of the problem: as detailed in the conclusions of Chapter 5, a reopening of the Biotech Directive affects too many stakeholders for too long a period of time to warrant this measure.

A minority view taken by two Experts is that clarification is needed as to the distinction between plant varieties and patentable plant related inventions (no patents are granted that cover plant varieties, the preferred option for those members). If the Commission is not able to clarify this distinction, then a full breeders' exemption and/or license of right should be provided, preferably as separate legislation. If this also is not feasible, a second fall-back option for those two Experts is that such provision is inserted into the Biotech Directive (see Conclusions of Chapter 5).

Enclosures to the subreport A:

Annex A1. Overview of actions (if any) EU Member States have undertaken to introduce a limited breeders' exemption in their patent law.

	What is the national instrument implementing Directive 98/44?	What is the definition of 'biological material'?	What is the definition of 'essentially biological processes'?	Exclusions from patentability related to plants	Are products obtained by essentially biological processes excluded from patentability?	Is there a provision expressly mentioning the patentability of plants?	Is there a 'breeders' exemption' in the national patent law?	Is there a provision on compulsory cross-licensing?	Has there been any parliamentary work in this field in the past 10 years?
PT	Decree-Law n.º 36/2003	Article 54 (4): "Biological material consists of any matter that contains genetic information and can be self-reproduced or reproduced in a biological system."	Article 54 (2): "Essentially biological processes for the production of plants or animals, means any process that consists fully of natural phenomena, such as crossing and	Article 52 (1) (b): "Materials or substances that already exist in nature" Article 52 (3) "(b): Plant or animal varieties as well as the essentially biological processes for the production of plants or	No.	Article 51 (1) mentions the scope of patentability: "New inventions are patentable if there is an industrial application even if it occurs on a product composed by or that contains biological material, or a process that allows for the production or use of that	No.	Yes, Article 109º (4).	No.

			selection. “	animals.”		biological material.”			
UK	Patents Act 1977 as amended by the Patents Regulations 2000 as well as the Patents and Plant Variety Rights regulations 2002	Section 130 of the Patents Act 1977 as amended ‘Biological material means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system’	Patents Act 1977 as amended Schedule A2 ‘essentially biological process means a process for the production of animals and plants which consists entirely of natural phenomena such as crossing and selection’.	Patents Act 1977 Schedule A2 3(f): “any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process.”	No.	Patents Act 1977 Schedule A2 4: “Inventions which concern plants or animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.”	Not yet but there is a consultation in progress with a view to amending the Patents Act 1977 to include this. The proposed wording is to insert in section 60 (meaning of infringement) in sub section 5 after para i ‘it consists of the use of biological material for the purposes of breeding or discovering and developing another plant	Yes, in the Patents and Plant Variety Rights (compulsory licensing) regulations 2002	No.

							variety'.		
CZ	206/2000 Sb	“biological material means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system”	“essentially biological process for production of plants or animals is the one that consists entirely of natural phenomena such as crossing or selection”	“plant varieties and animal varieties or essentially biological processes for the production of plants or animals”	No.	“Biotechnological inventions are patentable if they concern plants or animals if the technical feasibility of the invention is not confined to a particular plant variety or an animal variety”	No.	Yes.	No.
SW	Patent law (Patentlag) 1967:837 National plant breeders right legislation (Växtförädlarrättslagen 1997:306)	Law 1997:837, chapter 1, (1a §): “Biological material means material containing genetic information and capable of reproducing itself or being	Law 1997:837, chapter 1, (1a §): “Essentially biological processes of producing plants and animals means the processes consisting entirely of natural	Law 1997:837, chapter 1, (1a §), first sentence: “Patent will not be granted on plant varieties or animal breeds.” Second paragraph: “Patent will not be	No.	Yes, in law 1997:837, chapter 1, (1a §).	No.	Yes, both in patent law and in the PVP act.	Yes. Prior to the decision to adjust as well as incorporate additional text in the national patent law and plant variety right legislation an extensive round of hearings where

		reproduced in a biological system.”	phenomenon such as crossing or selection.”	granted on an essentially biological process for the production of plants or animals.”					performed, including a broad range of involved stakeholders. A comprehensive summary of comments and suggestions for adjustments where produced (unfortunately only available in Swedish). This document was distributed to the members of the Parliament and formed the base for the discussions and debates in the Parliament
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									prior to the formalization and decision on the final legislative text.
FR	Implemented into French law by law n°2004-1338. It has been implemented in several parts of the Code de la Propriété Intellectuelle (IPC).	Article L 611-10, paragraph 4° of IPC: "Is regarded as biological material the material which contains genetic information and which can reproduce itself or be reproduced in a biological system".	Article L 611-19 I 3° of the IPC: "are considered as essentially biological processes any process which deals exclusively with natural phenomenon such as crossing and selecting/selection"	Article L 611-19 I 2° IPC states that plant varieties as defined by Article 5 of EU Regulation n° 2100/94 are not patentable. Article L 611-19 I 3° states that essentially biological processes for the production of plants and animals are not patentable.	No.	Article L611-19 II IPC: "inventions which concern plants or animals are patentable if the technical feasibility of the invention is not confined to one plant or animal variety".	Yes. Article L 613-5-3 of the IPC provides that "the rights conferred by Articles L 613-2-2 and L 613-2-3 do not extend to acts accomplished in view of creating or discovering and developing new plant varieties."	Yes, Article L 613-15-1 of the IPC.	The French Senate adopted a resolution on the 17th January 2014 about placing on the market and patenting seeds and plant varieties. It states that the main IP tool for seeds and plant varieties is PBR (which stimulates innovation) and that the increasing amount of patents delivered is worrying (for

									breeders and farmers who can't be sure about the intellectual protection on a variety they use). Enhancing the use of patents would reduce the number of seed industries and thus be dramatic for the independence of States. Moreover, it is underlined that plants created through a traditional method/ process should not be patented.
DK	Law 412 of 30 May 2000 (no EN	§ 1 stk. 6: definition is very	§ 1 stk. 5: definition is very close	Plant varieties and essentially	Not excluded specifically.	§1 stk. 4.	No.	Yes § 46 a.	No.

	version available).	close to translation of Article 2 of Directive 98/44.	to translation from Directive 98/44.	biological processes are excluded from patentability					
PL	Industrial Property Law (PL: Prawo Własności Przemysłowej) On biotech inventions - chapter 9.	Art. 931: "biological material means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system"	Art. 29: "The process for the production of plants or animals, referred to in section (1)(ii), is essentially biological if it consists entirely of natural phenomena such as crossing or selection."	Art. 29: Patents shall not be granted for: (ii) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.	No.	Art. 932: "1. The following, in particular, shall be considered as biotechnological inventions eligible for patent protection: (iii) inventions which concern plants or animals, if the technical feasibility of the invention is not confined to a particular plant or animal variety."	No.	Article 82	No.
DE	Deutsches Patentgesetz	§2a German Patent Law „(3) Within the meaning of	§2a German Patent Law „(3) Within the meaning of	„§ 2a (1) Patents will not be granted for 1) plant	Yes, see article § 2a (1).	„§ 2a 2) Patents can be granted for inventions, 1) related to plants or animals,	Yes: „§ 11 The effect of the patent does not extend to 2a. the use	§ 24	Yes, most recently on the implementation of §2a (1) (this was

		this Act: 1) ,biological material' is material containing genetic information and is either self-reproducible or can be reproduced in a biological system;“	this Act: 1) an ,essentially biologic method' is a method for breeding plants or animals that consists entirely on natural phenomena like crossing or selection;“	varieties nor animal races nor essentially biological methods for breeding plants or animals nor plants or animals resulting from such procedures;“		provided the application of the invention is not limited to a particular plant variety or animal race;“	of biological material for the purposes of breeding, discovery or development of a new plant variety;“		done last year/2013) and the implementation of the directive itself in 2005.
IT	Directive 98/44/EC has been implemented in Italy late, in 2006, by virtue of the Decree Law n. 3 of 10 January 2006, then finally converted into Law n.	Art. 81-bis(1)a reads as follows: “biological material: a material containing genetic information and capable of reproducing itself or being	Art. 81-bis(2) reads as follows: “A process for the production of plants or animals is essentially biological when it consists fully of natural phenomena	Art. 45(4)b: “plant varieties and animal races and essentially biological processes for the production of animals or plants, included new plant varieties in	Not explicitly mentioned.	Art. 81 quarter: (The following may be patentable) “e) an invention regarding plants or animals or rather a plant group characterized by the expression of a specific gene and not of its whole genome, if its	No.	Art. 81-octies of Italian intellectual property code n. 30/2005 regulates compulsory licensing.	Discussions have been lengthy and extensive during the parliamentary works for the national adoption of Directive 98/44/EC. Italy was the last Member State to adopt the

	78 of 22 February 2006. Now incorporate d into the Italian Code for Industrial Property .	reproduced in a biological system".	such as crossing or selection".	respect of which the invention consists exclusively in genetically modifying a different plant variety, even if such modification is the result of a genetic engineering process".		application is not limited, from a technical standpoint, to the production of a specific plant variety or animal species, and in order to obtain thereof, not only essentially biological processes are used, in accordance with the provisions established by Article 170-bis, paragraph 6."			Directive. The works lasted for 8 years and the directive was then quickly adopted by the Government under the form a Law Decree, at the beginning of 2006, close to the end of Parliament legislature, in order to avoid a new procedure of infringement by the Commission. Italy supported the Netherlands in the European Court procedure for the annulment of
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									<p>Directive 98/44/EC (see Court case C-377/98); furthermore, the Commission started an action before the Court of Justice against Italy for the missed transposition of the Directive (see Court case C-456/03)</p> <p>In recent years, the matter of patentability of life (and plant varieties) sometimes re-emerges indirectly. Recently, during the debate on</p>
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									the Commission proposal for a new plant reproductive material regulation. However a real and wide debate on the matter does not exist.
GR	Presidential Decree # 321/24-9-2001	Article 2 1(a) of Decree 321/24-9-2001: "biological material: any material containing genetic information and capable of reproducing itself or being reproduced in a biological	Article 2(2) of Decree 321/24-9-2001: "A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection"	As in EPC	No.	Article 3(3) of Decree 321-24-9-2001: "Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety."	No.	Article 10 of Decree 321-24-9-2001.	No.

		system”							
HU	Implemented in the Hungarian patent act (law no. 1995:XXXIII)	Article 5/A (1): “Any material containing genetic information that is capable of reproducing itself or being reproduced in a biological system is considered to be biological material”	Article 6 (7): “A process for the production of plants or animals is essentially biological if it consists entirely of crossing, selection or any other natural process.”	Article 6 (4): “Patents cannot be granted on (a) plant and animal varieties; (b) essentially biological processes for the production of plants or animals.”	No.	Article 6 (5): “An invention regarding plants or animals is patentable if its technical feasibility is not confined to a specific plant or animal variety.”	No.	Yes, Article 32(3).	No.
NL	Dutch Patent Law (Rijksoctrooiwet 1995/ROW 1995)	Art. 1: biological material means any material containing genetic information and capable of reproducing itself or being	Partial definition in art. 3 sub 1 d: essentially biological processes, consisting entirely of natural phenomena such as crossing or	Article 3(1): “Not patentable are: c. plant or animal varieties, d. essentially biological processes, consisting entirely of natural	Yes.	Article 2a (2)(a): plants or animals, provided that the feasibility of the invention in technical point of view is not limited to a particular plant or animal varieties	Yes, Art. 53 b sub 2: The right referred to in Article 53a does not extend to acts with biological material that serve for the breeding, or discovering	Yes, art. 57 sub 5 and 6 ROW 1995 (see also art. 42 sub 2 of the Seeds and Planting Material Act/ZPW 2005)	Yes indeed. A first proposal for revision of the Rijksoctrooiwet 1995 in order to implement Directive 98/44/EC was presented to Parliament

		reproduced in a biological system	selection, for the production of plants or animals	phenomena such as crossing or selection, for the production of plants or animals <u>including the products thus obtained</u> , e. inventions, thereby infringing Articles 3, 8, j, 15, fifth paragraph, and 16, fifth paragraph, of the Convention on Biological Diversity;			and developing of other plant varieties.		28-5-1999, but because of many discussions at that time a revised proposal had to be made after which the implementation could be approved of (by Parliament 14-10-2004 and Senate 9-11-2004). The revised Rijksoctrooiwet 1995, implementing the Directive, thus came into force November 20th 2004. In the meantime the Dutch government had started an annulment
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									<p>action in regard to this Directive before the European Court of Justice, Case C-377/98 (none of the pleas were granted). Also questions in regard to the Directive were asked by the Dutch government to the European Commission by letter of 7-05-2003 (no formal reply received).</p> <p>In 2009 new discussions arose in Parliament on the collision between</p>
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									<p>patent rights and plant breeders rights on plants and the report “breeding business” was made in request of the Government. After that many discussions have taken place in Parliament, the Trojan report was made after consultation with stakeholders, and the support for a full (extensive) breeders exception was clearly expressed by all political</p>
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									<p>parties. By 2013 the Ministry of Economic Affairs (including Agriculture) took the position to aim at the inclusion of an extensive breeders exception on European level under the condition that other industries will not be damaged disproportionately.</p> <p>Recently (Decision of April 10 2004) a revision of article 53b of the Rijkssoctrooiwet 1995 has been</p>
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									<p>approved, introducing a limited breeders exception, which is seen by the Ministry of Economic Affairs as a first step in the right direction. Support for further actions is being sought by the Minister at other Member States, especially with Germany and France. At this moment the government is conducting a study to examine different</p>
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									scenarios in which the full breeders exception is somewhat restricted and the impact these scenarios have on the other industries.
RO	Patent Law no. 64/1991 Implementing Regulation of the Patent Law no. 64/1991	Art. 68 pgf. 2 "Biological material means, according to Art. 7 paragraph (2) letter a) of the Law, any material containing genetic information and which is self-reproducible or reproducibl	Art. 68 pgf. 8 "Essentially biological process for obtaining the plants or animals is a process wholly based on natural phenomena , such as crossing or selection."	Patent Law no. 64/1991, amended "Art. 9 - Patents shall not be granted under this Law in respect of: b) plant varieties and animal breeds, as well as the essentially biological processes for the production of plants or	No.	Implementing Regulation of the Patent Law no. 64/1991, amended Art. 70 pgf. 3 "According to Art. 7 paragraph (2) letter b) of the Law, the inventions relating to plants or animals are patentable, if the technical possibility for carrying out the invention is not confined to a certain plant	No.	Patent Law no. 64/1991, amended Art. 47 pgf. 5, 6	No.

		e within a biological system".		animals. This provision shall not apply to microbiological processes or products obtained thereby".		variety or animal breed."			
BE	It is part of the current Patent Law of 28 March 1984, which will, as from next year, be repealed as a result of all Belgian intellectual property laws being merged into Book XI of the so-called Code of Economic Law. Patent law will be dealt with in Part I of that	Article I.13(7) of the Code of Economic Law. The definition is the same as in Article 2(1) of the Biotech Directive.	Article I.13(9) of the Code of Economic Law. The definition is the same as in Article 2(2) of the Biotech Directive.	Both plant varieties and essentially biological processes are excluded from patentability . Article 4(1) of the Biotech Directive has been literally transposed in Article XI.5 of the Code of Economic Law.	No.	Article 4(2) of the Biotech Directive has been literally transposed in Article XI.5 of the Code of Economic Law.	No, there is no breeders' exemption in Belgian patent law. However, there is an experimental use exemption which is arguably broad enough to cover the same type of activity. Article XI.34(b) of the Code of Economic Law provides that "the	Article 12 of the Biotech Directive has been literally transposed in Article XI.37 of the Code of Economic Law.	No.

	<p>Book. The integrated text is not yet online. Here references are made to the new law.</p>						<p>rights conferred by a patent do not extend to acts that are committed on and/or with the subject matter of the patented invention for scientific purposes". The terms "on and/or with" indicate that it is allowed to use the patented invention as a tool to develop new products, without requiring a licence from the patentee. In terms of plant</p>		
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							breeding, this provision thus allows a breeder to use patented material for the purpose of breeding new varieties.		
AT	Patentgesetz 1970 StF: BGBl. Nr. 259/1970 (WV) idF BGBl. Nr. 137/1971 Fassung vom 02.10.2014 https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10002181	“biological material is material, which contains genetic information and is able to reproduce itself or can be reproduced in a biological system.”	“A process for plant breeding is basically biological, when it is covered by natural phenomena like crossing and selection.”	1) In general where humans are directly concerned 2) Plant varieties and animal races as well as essentially biological processes for breeding of plant varieties and animal races. Plant variety is defined according to Artikel 5 (EG) Nr.	No.	“Inventions, which are plants or animals can be patented, when the carrying out of an invention is technically not limited to a specific animal race or plant variety.”	No info	No info	No info

				2100/94 ABl. Nr. L 227 from 1. September 1994 S. 1, idF(EG) Nr. 2506/95, ABl. Nr. L 258 vom 28. Oktober 1995 S. 3.					

Annex A2. Overview of provisions in national patent law of EPC Member States on patentability of products directly obtained by an essentially biological process. The contributions regarding the national laws have been made by epi members of the Biotech Committee and by epi Board members.

Institut der beim Europäischen Patentamt zugelassenen Vertreter
Institute of Professional Representatives before the European Patent Office
Institut des mandataires agréés près l'Office européen des brevets

Ausschuss für Biotechnologische Erfindungen
Committee on Biotechnological Inventions
Commission pour les Inventions en Biotechnologie

National Laws on the Patentability of Plants

SUMMARY:

Art 53(b) EPC excludes from patentability plants or animal varieties or essentially biological processes for the production of plants or animals. Some national laws contain a provision excluding from patentability, besides essentially biological processes, the products derived thereof.

QUESTION (Q):

Is there a specific provision in the national law that excludes from patentability the plant products directly obtained by using an essentially biological process?

No	36
Yes	2

MS	National Law / EN translation	Remarks	Q
AL	<p>Law No. 9947 of 7 July 2008</p> <p>Art 6.2</p> <p>EN Translation</p> <p><i>Exceptions to patentability</i></p> <p><i>Patents shall not be granted in respect of:</i></p> <p><i>2. Plant or animal varieties or essentially biological processes for the production of plants or animals, without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.</i></p>	<p>Art 5.5 (c)</p> <p><i>Art 5 Patentable Inventions</i></p> <p><i>5. Biotechnological inventions shall also be patentable if they concern:</i></p> <p><i>c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.</i></p>	No
AT	<p>Patentgesetz 1970 BGBl. 1970/259 idF BGBl. I 2013/126 (Patentgesetz)</p> <p>§ 2(2) Patentgesetz</p> <p><i>§ 2. Patente werden nicht erteilt für:</i></p> <p><i>(2) Patente werden nicht erteilt für Pflanzensorten oder Tierrassen sowie für im wesentlichen biologische Verfahren zur Züchtung von Pflanzen oder Tieren. (...)</i></p> <p>EN Translation</p> <p><i>Patents shall not be granted for plants and animal varieties and</i></p>	<p>Products derived from essentially biological processes can be patented.</p>	No

	<i>for essentially biological processes for breeding plants and animals. [...]</i>		
BE	<p>Loi sur les brevets d'invention du 28 mars 1984 (Belgian Patent Act)</p> <p>Art 4- § 1er</p> <p><i>Sont exclus de la protection prévue par la présente loi:</i></p> <p><i>1) les obtentions végétales d'espèces ou de variétés bénéficiant du régime de protection institué par la loi du 20 mai 1975 sur la protection des obtentions végétales;</i></p> <p><i>2) les races animales;</i></p> <p><i>3) les procédés essentiellement biologiques d'obtention de végétaux ou d'animaux. La présente disposition ne s'applique pas aux procédés micro biologiques et aux produits obtenus par ces procédés.</i></p> <p>EN Translation</p> <p><i>The following shall be excluded from the protection afforded by this Law:</i></p> <p><i>(1) new plant varieties of species or varieties covered by the protection set up by the Law of May 20, 1975, for the protection of new plant varieties;</i></p> <p><i>(2) animal varieties;</i></p> <p><i>(3) essentially biological processes for the production of plants or animals. The present provision shall not apply to microbiological processes or to the products obtained thereby.</i></p>	<p>The new Patent Act which is still not in force in Belgium at the moment foresees the following amendment in Art 1:</p> <p><i>15° werkwijze van wezenlijk biologische aard voor de voortbrenging van planten of dieren : werkwijze voor de voortbrenging van planten of dieren die geheel bestaat uit natuurlijke verschijnselen zoals kruisingen of selecties;</i></p> <p>This clarifies that essential biological processes for the production of plants or animals are processes for the production of plants or animals which consist completely of natural phenomena such as crossings and selections.</p>	No
BG	<p>Bulgarian Patent Law</p> <p>Art 7 (1)</p> <p>EN Translation</p> <p><i>Exceptions to Patentability</i></p> <p><i>(1) Patents shall not be granted for:</i></p> <p><i>(...)</i></p> <p><i>3. plant varieties or animal varieties;</i></p>	<p>Patentability of biotechnological inventions is set in Art 7a (3):</p> <p><i>Inventions relating to plants or animals shall be considered patentable, if the technical realisation of the invention is not reduced to a certain plant or animal variety.</i></p>	No

	4. essentially biological processes for obtaining plants and animals.		
CH	<p>Bundesgesetz über die Erfindungspatente (Patentgesetz, PatG) vom 25. Juni 1954 Art 2(2)b</p> <p>Art 2(2)b PatG</p> <p><i>Von der Patentierung sind ferner ausgeschlossen:</i></p> <p>[...]</p> <p><i>b. Pflanzensorten und Tierrassen und im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren; unter Vorbehalt von Absatz 1 patentierbar sind jedoch mikrobiologische oder sonstige technische Verfahren und die damit gewonnenen Erzeugnisse sowie Erfindungen, deren Gegenstand Pflanzen oder Tiere sind und deren Ausführung technisch nicht auf eine bestimmte Pflanzensorte oder Tierrasse beschränkt ist.</i></p> <p>EN Translation</p> <p><i>[Excluded from patentability are:]</i></p> <p><i>b. Plant and animal varieties and essentially biological processes for the production of plants and animals; however, subject to the provisions of paragraph 1 microbiological or other technical processes and the products obtained thereby are patentable and so are inventions relating to plants or animals the working of which is not technically confined to a specific plant or animal variety.</i></p>	<p>An essentially biological process that comprises at least one non-biological, technical step that is required for arriving at the desired solution (e.g. irradiation, temperature shock), will be patentable and so will be the products obtained by that process (Art 8a PatG).</p> <p>Swiss patent law is, however, silent as to the patentability of products obtained by essentially biological processes.</p>	No
CY	<p>Patent Act of 1998 (Law 16(I)/98, as amended by Laws 21(I)/99, 153(I)/2000, 163(I)/2002 and 163(I)/2002).</p> <p>Article 5a</p> <p>EN Translation</p> <p><i>Essentially biological processes for the production of plants or animals are not patentable. (...) It is understood that the foregoing restriction shall not affect the patentability of patents</i></p>	<p>The Biotech Directive (98/44) has been implemented in Cyprus law, as an amendment to the Patent Act of 1998.</p>	No

	<i>having as an object a microbiological method or other technical methods or a product that is a result of such methods.</i>		
CZ	<p>Law No. 527/1990 Coll. on Inventions and Rationalisation Proposals (Patent Law)</p> <p>Section 4.b</p> <p>EN Translation</p> <p><i>Exclusions from patentability</i></p> <p><i>Patents shall not be granted in respect of:</i></p> <p><i>(...)</i></p> <p><i>b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes and the products thereof.</i></p>	<p>In two relevant Czech Laws (Nos. 527/1990 and 206/2000), there is no provision that explicitly excludes patentability of plants (or animals) obtained by essentially biological process. Consequently, the patentability of plant, wherein the plant is produced by essentially biological processes, would be an issue of official/judicial interpretation of the existing legal provisions. Unfortunately, up to now there is no relevant case law in the Czech Republic.</p> <p>Plant or animal varieties or essentially biological processes for the production of plants or animals are excluded from patentability by the Patent Law (Law No. 527/1990), nevertheless, the Law No. 206/2000, on the Protection of Biotechnological Inventions (which is an implementation of Biotech Directive 98/44/EC) in Section 2.b classifies plants and animals among the patentable inventions, “<i>if the technical feasibility of the invention is not confined to a particular plant or animal variety</i>”.</p>	No
DE	<p>Patentgesetz in der Fassung der Bekanntmachung vom 16. Dezember 1980 (BGBl. 1981 I S. 1), das zuletzt durch Artikel 1 des Gesetzes vom 19. Oktober 2013 (BGBl. I S. 3830) geändert worden ist</p> <p>§ 2a (1)1 Patentgesetz</p> <p><i>Patente werden nicht erteilt für</i></p> <p><i>1. Pflanzensorten und Tierrassen sowie im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren und die ausschließlich durch solche Verfahren gewonnenen Pflanzen und Tiere;</i></p> <p>EN Translation</p> <p><i>Patents shall not be granted for</i></p> <p><i>1. plant or animal varieties or for essentially biological processes for the production of plants or animals <u>and plants and animals exclusively obtained by such processes;</u></i></p>	<p><i>Bundestagsdrucksache 17/14222 regarding No. 1 (Amendment of Section 2a of the Patent Act – PatG):</i></p> <p><i>With this supplementation to Section 2a Subsection 1 Number 1 PatG, it will be clarified that, with regard to essentially biological processes for the production of plants and animals, <u>not only the processes but also plants and animals produced by such processes are not patentable, even if they are no plant or animal varieties which are anyhow excluded from patentability under Section 2a Subsection 1 Number 1 PatG.</u> The current version of this stipulation literally adopted Article 4 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions ([...] – Biopatent Directive). In this respect, the Enlarged Board of Appeal of the European Patent Office determined in its decision concerning patent cases “broccoli” and “tomato” (G2/07 and G1/08) of December 9, 2010 that the mere use of technical process steps for performing or supporting essentially biological processes do not render the processes patentable. However, in its decision, the Enlarged Board of Appeal</i></p>	Yes

	<p>(The underlined part has recently been added to the German provision. The amendment entered into force on 25 October 2013)</p>	<p><i>does not deal with the question of the patentability of products in the form of animal and plants produced by such animal- or plant related processes. The Federal Government is of the opinion that, according to the object and purpose of Article 4 of the Biopatent Directive, the patentability exclusion should mandatorily also apply to such animals and plants. The non-patentability of conventional breeding processes could otherwise be easily circumvented. In the interest of breeders and farmers, it shall therefore be clarified that plants and animals which immediately arise from their conventional breeding should not be covered by patents of third parties having generic product claims. The potential to obtain patent protection by the German industry – especially the chemical and pharmaceutical industry – should, however, not come restricted by anything going beyond the intention of this clarification. Products derived from biologically bred animals or plants, such as plant oils, should remain patentable provided they comply with the other patentability requirements. Only with a formulation which clearly relates the patentability exclusion of processes and products to the same matter, i.e. “plants and animals”, it will be possible to comply with the available scope for national regulations defined by the EU-Biopatent Directive which is particularly restricted to clarifications. In this context, the terms “plants and animals” do not only cover the produced animals and plants, but also material, such as seed, or in connection with animals, sperm, ovules and embryos, which is obtained by conventional biological processes and is useful for the production of plants and animals. The use of the term “exclusively” shall safeguard that undisputable patentable, especially genetically modified plants and animals will not be covered by the patentability prohibition because of the fact that they additionally underwent an essentially biological crossing and selection process.</i></p>	
DK	<p>Patents Act, cf. Consolidate Act No. 91 of 28 January 2009 LBK nr 91 af 28/01/2009 Gældende (Patentloven)</p> <p>Section 1(4)-1(6)</p> <p>EN Translation</p> <p><i>(4) Patents shall not be granted in respect of plant or animal varieties. Patents may, however, be granted for inventions, the subject-matter of which is plants or animals if the technical</i></p>	<p>The Danish patent law seems to be more “liberal” than the German law, and also slightly more than the Dutch law. This section was amended in the implementation of the Biotech Directive.</p>	No

	<p><i>feasibility of the invention is not confined to a particular plant or animal variety. In this Act a “plant variety” means a plant variety as defined in Article 5 of Council Regulation (EC) No. 2100/94 on Community plant variety rights.</i></p> <p><i>(5) Patents shall not be granted in respect of essentially biological processes for the production of plants or animals. In this Act an “essentially biological process” means a process consisting entirely of natural phenomena such as crossing or selection. Patents may, however, be granted for microbiological processes or other technical processes or products obtained by such processes. In this Act a “microbiological process” means any process involving microbiological material, performed on microbiological material or resulting in microbiological material.</i></p> <p><i>(6) Inventions may be patentable even if they relate to a product consisting of or containing biological material or to a process by means of which biological material is produced, processed or used. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject-matter of an invention even if it previously occurred in nature. In this Act “biological material” means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.</i></p>	
EE	<p>Estonian Patent Act of March 16, 1994</p> <p>Art 7</p> <p>EN Translation</p> <p><i>Non patentable inventions</i></p> <p><i>(...)</i></p> <p><i>(2) The following biotechnological inventions shall not be protected by a patent:</i></p> <p><i>(...)</i></p>	No

	<p>5) essentially biological processes for the derivation of biological materials, plants or animals, except microbiological processes for the derivation of micro-organisms;</p> <p>6) inventions the application of which is confined to a single plant or animal variety.</p> <p>(3) For the purposes of this Act, “essentially biological process for the derivation of a biological material, plant or animal” means a process which consists entirely of natural phenomena such as crossing and selection.</p>		
ES	<p>Law No. 11/1986 of March 20, 1986 on Patents <i>Ley 11/1986, de 20 de marzo de 1986, por la que se aprueba la Ley Patentes y Modelos de Utilidad</i></p> <p>Art 5.3</p> <p>EN Translation <i>Non-patentable subject matter are:</i> 3. Essentially biological processes for the production of plants or animals. For these purposes essentially biological processes means processes which consist entirely of natural phenomena such as crossing and selection.</p> <p><i>The previous paragraph will not affect the patentability of inventions related to a microbiological method, or to any other technical method, or to a product obtained by such methods.</i></p>	<p>Art 5.3 of the Spanish Patent Law excludes essentially biological processes but <u>not</u> the products.</p> <p>There is a proposal for changing the Spanish patent law in the near future, but this provision will not be amended.</p>	No
FI	<p>Finnish Patents Act, No. 550 of December 15, 1967 Chapter 1, Section 1 as amended 30.6.2000/650 and 18.11.2005/896</p> <p>EN Translation <i>Anyone who has, in any field of technology, made an invention which is susceptible of industrial application, or his or her successor in title, is entitled, on application, to a patent and</i></p>	<p>Finnish Patents Act excludes from patentability plant or animal varieties and essentially biological processes for the production of plants or animals. There is no legal provision excluding the products derived from essentially biological processes from patentability.</p> <p>The Biotech Directive was implemented to Finnish Patents Act by amendment which entered into force on 30th June 2000. The implementation was done in cooperation with other Nordic countries. Therefore the legislation regulating the</p>	No

	<p><i>thereby to the exclusive right to exploit the invention commercially, in accordance with this Act (18.11.2005/896). (...)</i></p> <p><i>Patents shall not be granted for plant or animal varieties. Inventions which concern plants or animals shall nevertheless be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety. The concept of plant variety within the meaning of this Act is defined by Article 5 of Council Regulation (EC) No 2100/94 on Community plant variety rights.</i></p> <p><i>Patents shall not be granted for essentially biological processes for the production of plants or animals. For the purposes of this Act a process for the production of plants or animals shall be considered essentially biological if it consists entirely of natural phenomena such as crossing or selection. What is said above shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process. For the purposes of this Act 'microbiological process' means any process involving or performed upon or resulting in microbiological material.</i></p> <p><i>Inventions shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature. For the purposes of this Act 'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.</i></p>	<p>patenting of biotechnological inventions is very similar in different Nordic countries.</p>	
FR	<p>French Intellectual Property Code (CPI)</p> <p>Art L611-19</p>	<p>Following the EU Directive N°98/44 of July 6, 1998 on biotech inventions, the French Parliament enacted a law on bioethics on August 6, 2004 (J.O n° 182 of August 7, 2004, which deals with the human body (Article L.611-18 of the French</p>	No

	<p>EN Translation</p> <p><i>The following shall not be patentable:</i></p> <p><i>1^o animal varieties;</i></p> <p><i>2^o plant varieties as defined in Article 5 of Regulation (EC) No. 873/2004 introducing new rules governing intellectual property ownership of Community plant variety rights;</i></p> <p><i>3^o essentially biological processes for the production of plants and animals. A process that consists entirely of natural phenomena such as crossing or selection shall be regarded as biological process.</i></p>	<p>Intellectual Property Code)) and another law on the protection of biotechnological inventions on December 8, 2004 (J.O n° 286 of December 9, 2004, which deals with plants and animals (Article L.611-19 of the French Intellectual Property Code)).</p> <p>The new provisions recognize that biological material (i.e. any material containing genetic information and capable of reproducing itself or being reproduced in a biological system) may be involved in a patentable invention, provided that it can be isolated from its natural environment or produced by means of a technical process and that it complies with the traditional patentability requirements (the invention must be new, involve an inventive step, and be susceptible of industrial applications).</p> <p>Up to date there is no case law in France with respect to the patentability of plants or plant material product claims, wherein the plants or plant materials are produced by an essentially biological non-patentable process.</p>	
GB	<p>UK Patents Act 1977</p> <p>Section 76A and Schedule A2</p> <p><i>76A Biotechnological inventions</i></p> <p><i>(1) Any provision of, or made under, this Act is to have effect in relation to a patent or an application for a patent which concerns a biotechnological invention, subject to the provisions of Schedule A2.</i></p> <p><i>(2) Nothing in this section or Schedule A2 is to be read as affecting the application of any provision in relation to any other kind of patent or application for a patent.</i></p> <p>SCHEDULE A2 BIOTECHNOLOGICAL INVENTIONS</p> <p><i>(...)</i></p> <p><i>3 The following are not patentable inventions—</i></p> <p><i>(...)</i></p> <p><i>(f) any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process.</i></p>		No

	<p><i>4 Inventions which concern plants or animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.</i></p> <p><i>11 In this Schedule:</i></p> <p><i>“essentially biological process” means a process for the production of animals and plants which consists entirely of natural phenomena such as crossing and selection;</i></p> <p><i>(...)</i></p>		
GR	<p>Law No. 1733/87 (FEK 171 A' of 22.09.1987)</p> <p>"Technology transfer, inventions, and technological innovation" as amended by Art 18, of Law No. 1739/1987 (FEK 201, A' of 20.11.1987)</p> <p>Article 5.8.b</p> <p>EN Translation</p> <p><i>Patents shall not be granted in the following cases:</i></p> <p><i>b. plant or animal varieties or biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.</i></p>	<p>The Greek national law "Technology transfer, inventions, technological innovation and establishment of the Commission of Atomic Energy" (number 1733/1987 as in force) contains a provision excluding the varieties of plants and animals from patentability, besides essentially biological and microbiological processes and the products derived therefrom. The products derived from essentially biological processes for the production of plants or animals are not excluded from patentability. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection. Inventions relating to plant (or animal) varieties have patentability, only if the technical feasibility of the invention is not confined to a particular plant (or animal) variety. See presidential Decree 321/2001, the implementation of the EU Directive 98/44/EC on the legal protection of biotechnological inventions (relevant Art 2 -3).</p>	No
HR	<p>Croatian Patent Act</p> <p>Art 6.1</p> <p>EN Translation</p> <p><i>Excluded from patent protection shall be:</i></p> <p><i>1. inventions which concern animal breeds, plant varieties and essentially biological processes for the production of plants or animals, with the exception of inventions which concern non-biological and microbiological processes and products resulting from such processes, as provided for in Article 5, paragraph (4) of this Act; a microbiological process shall imply, under this Act, any process involving or performed upon or resulting in</i></p>	<p><i>Art 5.4) (...) An invention which concerns plants or animals shall be considered patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety and if the process for carrying out the invention is not essentially biological.</i></p>	No

	<i>microbiological material.</i>		
HU	<p>Hungarian Patent Act (Act XXXIII of 1995 on the protection of inventions by patents)</p> <p>Art 6.4.b</p> <p>EN Translation</p> <p><i>4. The following shall not be patentable:</i></p> <p><i>(a) plant varieties [Article 105(a)] and animal breeds;</i></p> <p><i>(b) essentially biological processes for the production of plants or animals.</i></p> <p><i>5. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant variety or animal breed.</i></p> <p><i>(...)</i></p>	Art 6 of the Hungarian Patent Act excludes from patentability only essentially biological processes for the production of plants and animals. Hungary has no legal provision excluding the products derived from essentially biological processes from patentability.	No
IE	<p>Irish Patents Act 1992</p> <p>Section 10b</p> <p><i>A patent shall not be granted in respect of (...)</i></p> <p><i>b) a plant or animal variety or an essentially biological process for the production of plants or animals other than a micro-biological process or the products thereof.</i></p>	The Irish Patents Act 1992 at present does not contain provisions which exclude plants and animals exclusively obtained by such processes.	No
IS	<p>Icelandic Patents Act No 17/1991</p> <p>Art 1</p> <p>EN Translation</p> <p><i>(...) A patent shall not be granted for plant or animal varieties. It is however possible to grant patents for inventions pertaining to plants and animals if the implementation of the patent is not confined for technical reasons to a particular plant or animal variety. In this Act, plant variety refers to a plant variety as it is defined in the Act on Plant Variety Rights, No. 58/2000.</i></p> <p><i>A patent shall not be granted on an essentially biological process for producing plants or animals. By an essentially</i></p>	The relevant provisions are almost identical to the Danish Patent Act.	No

	<p><i>biological process, this Act refers to a method that on the whole is based on natural phenomena such as crossing and selection [...]"</i></p>		
IT	<p>Italian Industrial Property Code (IIPC) <i>Decreto Legislativo 10 febbraio 2005, n. 30 Codice della proprieta' industriale, a norma dell'articolo 15 della legge 12 dicembre 2002, n. 273 and further amendments</i> Art 45.4.b</p> <p>EN Translation <i>Patentable subject matter</i> (...) 4. <i>It cannot be a patentable subject-matter</i> (...) b) <i>plant varieties and animal breeds and essentially biological processes for production of animals or plants, including new plant varieties with respect to which the invention consists only of the genetic modification of another plant variety, even if such modification results from a process of genetic engineering.</i> 5. <i>The provision of paragraph 4 shall not apply to microbiological processes and products obtained by these processes.</i></p> <p>As to plants or group of plants, Art 81 IIPC recites:</p> <p><i>Art 81-quater Patentability</i> 1. <i>It can be patentable, subject to fulfilment of novelty, inventive step and industrial applicability requirements:</i> (...) e) <i>an invention relating to plants or animals or a plant grouping characterized by the expression of a specific gene and not by its whole genome, provided that their application is not limited, from a technical standpoint, to the obtainment of a particular</i></p>	<p>Plant varieties are clearly excluded from patent protection.</p> <p>Then exclusion of patentability of plants is limited to plants univocally used for the production of plant varieties <u>and</u> obtained solely through essentially biologically processes.</p>	No

	<i>plant variety or animal species and that they are not obtained by means of essentially biological processes only, (...)</i>		
LI	See under “CH”		No
LT	<p>Lithuanian Patent Law (Law on Patents of 18 January 1994, No. I-372 as changed on: 08 November 1994; 09 and 23 December 1997; 15 June 2000; 21 December 2000; 30 October 2001; 30 June 2005; 08 June 2006; 10 May 2007; 23 December 2010)</p> <p>Art 5.1 paragraph 2)</p> <p>EN Translation <i>Patents should not be granted for (...)</i> <i>2) plant or animal varieties or essentially biological methods for obtaining thereof.</i> <i>This provision does not apply to microbiological production methods of plants or animals and to the products obtained by such methods, in case the technical implementation of the invention is not limited to a particular plant or animal variety.</i></p>	What is emphasized in bold appeared as from 30/06/2005.	No
LU	<p>Loi du 20 juillet 1992 portant modification du régime de brevets d'invention telle que modifiée par la loi du 24 mai 1998 et par la loi du 11 août 2001 et par la loi du 7 avril 2006 et la loi du 25 avril 2008</p> <p>Art 5bis</p> <p>EN Translation <i>1. Not patentable are:</i> <i>a) Plant and animal varieties</i> <i>b) Essentially biological methods for obtaining plants or animals.</i> <i>2. Inventions concerning plants or animals are patentable if the technical implementation of the invention is not limited to a</i></p>		No

	<p><i>particular plant or animal variety.</i></p> <p><i>3. Paragraph 1, item b), does not affect the patentability of inventions related to a microbiological method, or to other technical methods, or to a product obtained by such methods.</i></p>		
LV	<p>Patent Law of the Republic of Latvia (in force since 01.03.2007)</p> <p>Art. 10 (Biotechnological Inventions)</p> <p>EN Translation</p> <p><i>1. A patent shall be granted to biotechnological inventions:</i></p> <p><i>1.1. containing biological material isolated from its natural environment or acquired with the help of a technical method, even if it has been previously met in nature;</i></p> <p><i>1.2.. pertaining to plants or animals if the technical nature of the invention does not confine itself to some specific plant or animal variety; and</i></p> <p><i>1.3. pertaining to microbiological or other technical method or a product acquired with such a method if it is not a plant or animal variety.</i></p> <p><i>2. A patent shall not be granted to plant or animal varieties or to the basically biological methods for the acquisition of plant or animal varieties.</i></p>		No
MC	Patent law in Monaco N°606 of June 20, 1955	There is no specific provision in the national law that excludes from patentability the plant products directly obtained by using an essentially biological process	No
MK	<p>Macedonian Law on Industrial Property</p> <p>Art 26.1</p> <p>EN Translation</p> <p><i>A patent may not protect an invention:</i></p> <p><i>1) which relates to new animal and plant varieties and essentially biological processes for the production of animals or plants, with the exception of biotechnological inventions, for which the technical feasibility is not restricted to a certain type,</i></p>		No

	<p><i>and microbiological processes and products generated from such processes;</i> <i>(...)</i></p>		
MT	<p>Maltese Patents and Designs Act (Cap. 417 Laws of Malta) Art 4.5</p> <p><i>A patent shall not be granted in respect of: (...)</i> <i>e) plant and animal varieties:</i> <i>Provided that patents shall not be granted for plant varieties only after a new form of plant variety protection is introduced in such form as may be prescribed:</i> <i>Provided further that a patent may still be granted for a plant variety in respect of which a patent application is still pending on the date that a new form of plant variety protection is prescribed;</i> <i>(f) essentially biological process of the production of plants or animals:</i> <i>Provided that this is without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process;</i> <i>6. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.</i> <i>(...)</i></p>		No
NL	<p>Dutch Patent Act 2010 (Rijksoctrooiwet 2010) Art 3.1.d</p> <p>EN Translation <i>No patents shall be issued for:</i> <i>(...)</i> <i>(c) plant or animal varieties,</i> <i>(d) essentially biological processes, entirely consisting of natural phenomena such as crossings and selections, for the production</i></p>	<p>Unlike the EPC and in conflict with the Biotech Directive (98/44 EC), the Dutch Patent Act 2010 excludes from patentability plants or animals produced by essentially biological processes, even if the technical feasibility of the invention is not confined to a particular plant or animal variety</p>	Yes

	<i>of plants or animals as well as the products obtained as a result thereby (...)</i>		
NO	<p>The Norwegian Patents Act, no 9 of December 15, 1967 (last amending Act on July 1, 2013)</p> <p>Section 1</p> <p>EN Translation</p> <p><i>Within any technical field, any person who has made an invention which is susceptible of industrial application, or his successor in title, shall, in accordance with this Act, have the right on application to be granted a patent for the invention and thereby obtain the exclusive right to exploit the invention commercially or operationally.</i></p> <p><i>Subject matters not regarded as inventions include anything which merely consists of:</i></p> <ol style="list-style-type: none"> <i>1. discoveries, scientific theories and mathematical methods;</i> <i>2. aesthetic creations;</i> <i>3. schemes, rules or methods for performing mental acts, playing games or doing business, or programs for computers;</i> <i>4. presentations of information.</i> <p><i>Inventions may also constitute patentable inventions when they concern a product consisting of or containing biological material, or a process by means of which biological material is produced, processed or used. Biological material, which is isolated from its natural environment or produced by means of a technical process, may be the subject of an invention even if it already occurs in nature. Biological material means, for the purpose of this legal text, material that contains genetic information, and can reproduce itself or be reproduced in a biological system.</i></p> <p><i>A patent cannot be granted in respect of plant or animal</i></p>	<p>Products obtained by microbiological or other technical processes are patentable, but the law does not say anything of products obtained by essentially biological processes.</p> <p>Also relevant is the patent regulation's definition of "plant variety";</p> <p>Section 88 Definition of plant variety</p> <p>Under the patent act and regulation a plant variety is understood to be a stock of plant within a single botanical taxon of the lowest rank, which</p> <ol style="list-style-type: none"> 1. Can be defined on the basis of the characteristics resulting from a given genotype or combination of genotypes, 2. can be distinguished from any other population of plants on the basis of the occurrence of at least one of the said characteristics, and 3. can be considered as a unit with regard to the ability to reproduce unchanged. <p>The existence of characteristics as mentioned in first paragraph no. 1, can be invariable or variable between variety constituent parts of the same kind, provided that the variation level is due to the genotype or combination of genotypes.</p>	No

	<p><i>varieties. Inventions that concern plants or animals may, however, be patentable if usage of the patent is not technically limited to one particular plant or animal variety. The King may, by regulation, determine what should be considered a plant or an animal variety.</i></p> <p><u><i>A patent cannot be granted for what are essentially biological processes to produce plants or animals. An essentially biological process means, for the purpose of this legal text, a process, which consists entirely of natural phenomena such as crossing or selection. A patent may, on the other hand, be granted for microbiological or other technical processes or for a product produced by such processes. A microbiological process means, for the purpose of this legal text, any process involving, performed upon or resulting in the production of microbiological material.</i></u></p> <p><i>A patent shall not be granted for methods for surgical or therapeutic treatment or diagnostic methods, practiced on humans or animals. This provision shall not prevent the grant of patents for products, including substances and compositions of substances, for use in such methods.</i></p>		
PL	<p>Industrial Property Law (Law of June 30, 2000 on Industrial Property (as last amended by Law of 23 January 2004, and Law of June 29, 2007))</p> <p>Art 29</p> <p>EN Translation</p> <p><i>Patents shall not be granted for: (...)</i></p> <p><i>2) plant varieties or animal breeds as well as purely biological processes of or animals breeding; this provision does not apply to microbiological processes for breeding or products obtained by these processes.</i></p>	<p>While essentially biological processes of plants or animals production are excluded from patentability, there is no explicit exclusion of patentability of products derived from essentially biological processes.</p> <p>Furthermore, biotechnological inventions directed to plants or animals other than strictly plant variety or animal breed are patentable. I.e.:</p> <p><i>Art 93.1. Patentable biotechnological inventions are in particular: (...)</i></p> <p><i>3) inventions relating to plants or animals if technical feasibility of the invention is not confined to a particular plant variety or animal breed.</i></p>	No

	<p>2. A process for plants or animals breeding referred to in Art 29.1. is purely biological if it consists entirely of crossing, selection or other natural phenomena.</p>		
PT	<p>Portuguese Industrial Property Code (IPC) - (approved by Decree-Law 36/2003 of 5 March and amended by Decree-Law 318/2007 of 26 September, Decree-Law 360/2007 of 2 November, Decree-Law 143/2008 of 25 July and Law 16/2008 of 1 April)</p> <p>Art 53.3.b</p> <p>EN Translation</p> <p><i>Limitations regarding patents</i></p> <p>3. The following shall also not be the subject matter of a patent: (...)</p> <p>b) Plant or animal varieties, as well as essentially biological processes for the production of plants or animals; (...)</p> <p><i>Art 54 Special cases of patentability</i></p> <p>1. The following shall be patentable: (...)</p> <p>d) An invention concerning plants or animals, if its technical feasibility is not confined to a particular plant or animal variety;</p> <p>e) A biological material isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature;</p> <p>f) An invention concerning a microbiological process or other technical processes, or products obtained by means of such processes.</p> <p>2. An essentially biological process for the production of plants or animals means any process consisting entirely of natural phenomena such as crossing or selection. (...)</p>	<p>These matters are set forth in greater detail in the “Guide to Procedures concerning Technological Rights”, published by INPI, which states as follows:</p> <p>5.2.1. Plant varieties</p> <p>The term “plant variety” is defined in Rule 26(4) EPC. A patent will not be granted if the material claimed is directed to a specific plant variety or to specific plant varieties. However, if the invention relates to plants and animals and if the technical feasibility of the invention is not confined to a particular plant or animal variety, the invention is patentable (see IV, 3.2) [Rule 26(4), Rule 27(b) EPC]. When a claim to a process for the production of a plant variety is examined, Article 97(2) IPC (Article 64(2) EPC) shall not be taken into consideration (see G1/98, OJ 3/2000, 111). Therefore, a claim to a process for the production of a plant variety (or plant varieties) is not a priori excluded from patentability simply because the resulting product constitutes or may constitute a plant variety.</p> <p>5.2.2. Processes for the production of plants or animals</p> <p>A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection. To give some examples, a method of crossing, interbreeding or selectively breeding, say, horses, involving merely selecting for breeding and bringing together those animals having certain characteristics would be essentially biological and therefore unpatentable. On the other hand, a process of treating a plant or animal to improve its properties or yield or to promote or suppress its growth, e.g. a method of pruning a tree, would not be essentially biological since although a biological process is involved, the essence of the invention is technical; the same could apply to a method of treating a plant characterised by the application of a growth-stimulating substance or radiation. The treatment of soil by technical means to suppress or promote the growth of plants is also not excluded from patentability (see also IV, 4.8.1) [Rule 26(5) EPC].</p>	No

RO	<p>Romanian Patent Law 64/1991 Art 9.b</p> <p>EN Translation <i>Patents shall not be granted under this Law in respect of:</i> (...) <i>b) plant varieties and animal breeds, as well as the essentially biological processes for the production of plants or animals. This provision shall not apply to microbiological processes or products obtained thereby;</i> (...)</p>	<p>Art 7.b-c</p> <p><i>Art 7 - A patent shall be granted for any invention having as a subject-matter a product or a process, in all technological fields, provided that it is new, involves an inventive step and is susceptible of industrial application.</i> <i>Inventions in the field of biotechnology shall be patentable if they relate to:</i> (...) <i>b) plants or animals, if the technical feasibility of the invention is not limited to a particular plant variety or animal breed;</i> <i>c) a microbiological process or other technical process or a product, other than a plant variety or animal breed, obtained by means of said process.</i></p>	No
RS	<p>Serbian Patent Law (Issued in "Official Gazette of the Republic of Serbia", no. 99/11, dated December 27th 2011); in force since January 4th, 2012</p> <p>Art 9.3</p> <p>EN Translation <i>Exceptions to Patentability</i> <i>A patent shall not be granted in respect of:</i> (...) <i>3. a plant or animal variety or an essentially biological process for the production of a plant or animal, provided that this provision shall not apply to microbiological processes or the products obtained by means of such process.</i> (...) <i>Essentially biological process referred to in item 3) of this Article for the production of plants or animals is a process consisting entirely of natural phenomena such as crossing or selection.</i></p>		No
SE	Sweden Patent Act No.837 of 1967	Under Swedish law, there is no provision excluding products derived from essentially biological processes.	No
SI	Intellectual Property Act Art 16		No

	<p>EN Translation <i>Subject-matter of short-term patent protection</i> <i>(1) With the exception of processes, plant varieties and animal breeds, a short-term patent may be granted for inventions which are new, susceptible of industrial application and are the result of a creative effort.</i></p>		
SK	<p>Slovak Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts as Amended (The Patent Act) Art 6.1</p> <p>EN Translation <i>Exceptions to patentability</i> <i>1. Patents shall not be granted to</i> <i>a) plant and animal varieties,</i> <i>b) essentially biological processes for creation plants or animals,</i> <i>(...)</i></p>	<p><i>Art 3 Definition of terms</i> <i>For purposes of this Act</i> <i>(...)</i> <i>c) essentially biological process for creation plants or animals shall mean a process based exclusively on natural phenomena such as breeding or selection,</i> <i>(...)</i></p> <p><i>Article 5</i> <i>Patentability of inventions</i> <i>1. Patents shall be granted for inventions from all fields of technology, which are new, involve inventive activity and are industrially applicable.</i> <i>2. Patents pursuant to paragraph 1 shall be also granted for biotechnological inventions concerning to a product consisting of or containing biological material, or to a process by means of which biological material is produced, processed or utilised, including cases when invention relates to (...)</i> <i>b) a plant or an animal, if a technical feasibility of an invention is not reduced to a particular plant or animal variety (Act No 132/1989 Coll. on Protection of Rights to New Plant and Animal Variety),</i> <i>(...)</i></p>	No
SM	<p>Industrial Property Consolidation Act of the Republic of San Marino, Law n. 79 of 25 May 2005 Art 2.4</p> <p>EN Translation <i>(Subject-matter of the patent and exclusions from patentability)</i></p>	<p>The wording excluding plants and animals exclusively obtained by such processes present in DE and NL law is not present in San Marino Act</p>	No

	<p>4. <i>The following inventions are not patentable:</i> <i>(...)</i> <i>c) inventions concerning animal varieties or essentially biological processes for the production of animals varieties; this provision shall not apply to microbiological processes and the products thereof;</i> <i>(...)</i> 5. <i>An essentially biological process means a process, which consists entirely of natural phenomena such as crossing or selection.</i></p>		
TR	<p>Turkish Decree Law 551 Art 6</p> <p>EN Translation <i>(Non-Patentable subject matter and Inventions)</i> <i>(...)</i> <i>Patent shall not be granted for inventions in respect of following subject matter.</i> <i>b) Plant or animal varieties/species or processes for breeding/plant or animal varieties/species, based mainly on biological grounds.</i></p>		No

Annex A3

Dissenting opinion expressing disagreement with the majority opinion of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering in regard to the report on plant patents

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The essence of this Opinion is supported by Ingrid Schneider.

Summary

This document is a dissenting opinion to the report on patents in the field of plant breeding (hereinafter referred to as the "*Report*"), expressing disagreement with the majority opinion of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering (E02973).

As in the *Report*, this opinion is focused on topics that are relevant in the context of patents on plants and animals stemming from processes of breeding that are considered to be essentially biological. Detailed recommendations for political action are provided. The most relevant points in the dissenting opinion - in contrast to those in the *Report* - are that:

- The EPC (European Patent Convention) should not be interpreted in a way to allow patents on plants and animals.
- Directive 98/44/EC was primarily adopted to enable patents on plant-related inventions in the context of genetic engineering, but not in conventional breeding.
- The criteria developed by the European Patent Office (EPO) in the granting of patents on genetically engineered plants cannot be applied to conventional breeding.
- The *Report* fails to sufficiently discuss how more legal certainty can be achieved. In this regard, a clear definition of "essentially biological processes" would have been crucial. Further plant characteristics that can be achieved by conventional breeding have to be excluded from scope of patents and a whole content approach has to be applied in examination of patent applications.
- New technological developments in plant breeding are not the main factor driving current developments that are leading to an increasing number of patents in conventional breeding. In this context, the *Report* systematically under-represents the role of agrochemical companies that have entered the plant breeding sector in recent decades, and follows a different IP strategy than the traditional breeders.
- The *Report* does not sufficiently analyse the downstream consequences of patents granted on conventional breeding affecting farmers, consumers, food producers, food security and

the agro-ecological systems.

- A first step should be to establish new binding rules for the interpretation of current law without changing the text of the Directive. The new interpretation of the Directive could either be achieved politically through the Commission or by EU Member States taking action via the Administrative Council of the EPO.

There is a strong need for a better balance in patent law to meet the interests of the broader public, the needs of traditional breeders, farmers, food producers and consumers. This requires the Commission setting strong priorities and to taking the first initiative in strengthening the prohibitions in Article 53(b) EPC by giving guidance for interpretation of the EU Patent Directive. The next step could be a thorough revision of the EU Patent Directive in order to set out robust and legally defined limits of patentability. Contrary to the views expressed in the majority opinion of the Expert Group, taking no political action is not and cannot be an option.

1. Introduction

The *Report* drawn up by the Expert Group does not address important issues that are necessary to understand the context, the problems and consequences of current patent law as interpreted and applied by the European Patent Office. Furthermore, the *Report* does not address in detail the range of possible political action that should be taken to overcome the current problems.

Clearly, the composition of the Expert Group selected by the Commission was one of the reasons why the final version of the *Report* was drawn up in this way. Indeed, there was no expert included in the group to represent farmers or consumer organisations, and only one expert included in the group was selected from a broad range of non-profit civil society organisations active in this field. Regardless of why the members of the Expert Group were chosen as they were by the Commission, this is a factor that needs to be addressed, since not only the conclusions drawn, but also the arguments presented in the *Report* were mostly selected by majority votes. In consequence of the composition of the group, also the *Report* to some extent is biased in its reasoning, findings and recommendations.

This dissenting opinion elaborates on only some of the arguments that were introduced into the discussion, but not covered in the *Report*. Further, in examining possible political actions and activities it will address in more detail what kind of political actions and activities the Commission should take to overcome the current problems.

2. Legal analysis: Does the EPC allow for patents on plants and animals?

In the *Report* it is stated that

“the entry into force of the European patent convention predates the first transgenic plant by 10 years, meaning that the legislator could not have had the intention to limit patentability of plant related inventions to transgenic plants and processes of genetic modification.”

This statement creates the impression that patents on plants and animals have always been granted in Europe, and were not restricted to those plants derived from genetic engineering.

The above statement, however, is misleading. The wording chosen by the European Patent Convention (EPC), gives no indication that the legislator wanted to allow patents on plants and animals in general at the time, when it was adopted in 1973. A historical examination taking into account legal comments published during the first fifteen years after the EPC was adopted, shows that standard commentaries (such as well-known commentaries of Benkard, Patentgesetzkomentar, 8. Auflage 1989, Beck; Schulte Patentgesetzkomentar, Heymanns, 2. - 4. Auflage, 1987; Singer, Europäisches Patentübereinkommen, 1989, Heymans) come to the conclusion that plants and animals are not patentable.

The same conclusion can be drawn from legislative action taken by Contracting States when the EPC was adopted into national legislations. For example, in 1976 when national patent law was adopted in Switzerland, a statement made by the Swiss Bundesrat showed clearly that plants and animals were regarded as non-patentable: “([Es] können nicht patentiert werden: auf dem Gebiet des Pflanzen- und Tierreichs: die Lebewesen selbst.”) A similar explanation can be found in the the German Parliament’s Bundestagsdrucksache Nr. 8/2087 of 7 September 1978 which concerns interpretation of the German patent law.

The EPO had already granted some patents on plants in the 1980s / 1990s. These patents show that at least some examiners at the EPO were of the opinion – in contrast to the references made above - that patents on plants could be granted. Thus, the EPO actively started to widen the area of patentability. By making decisions such as T320/87, which in effect made the patentability of specific processes of hybrid production possible, the EPO attempted to establish a new legal interpretation of Article 53(b). This development triggered many legal and political controversies. As decisions T 356/93 and T1054/96 show, the interpretation of 53(b) was still not settled when Directive 98/44/EC was adopted.

The EPO’s Technical Board of Appeal decision on the patentability of plants (T356/93) concluded that patents that inevitably extended to plant and animal varieties, are regarded as being in contradiction to the wording of Article 53(b) EPC. In the light of this decision, and in result of the decision T1054/96 (which then led to the Decision G1/98), the granting of patents on plants and animals officially was stayed (while in practise the EPO not completely stopped to grant these patents).

Further, it has to be acknowledged that not only Art. 53(b) but also Art 53(a) EPC triggered major legal and political controversies in the 1990s. Many oppositions were filed against the patent on the so-called oncomouse (EP0169672) under Art. 53(a), EPC, because patents on plants and animals generally were regarded as being in conflict with ordre public and morality. To conclude, the question to which extent plants and animals are patentable under the EPC was not finally decided before Directive 98/44/EC was adopted and taken into the Implementation Regulations of the EPC. The oppositions and appeals against the patent of the oncomouse (T0315/ 03) as well as the decision G1/98 were finally decided after the EU Directive was adopted and became part of the Implementation Regulations of the EPC. It has to be assumed that both, G1/98 (Novartis) as well as T0315/ 03 (oncomouse) were influenced by the wording of the Directive and the new Implementation Regulations. In any case, G1/98 and T 0315/03 cannot be interpreted as a decision made independently of the wording of the EU Directive.

In conclusion, the EPC as adopted in 1973, should not be interpreted in such a way that it would generally allow patents on plants and animals. It was only after the EU Directive was adopted and became part of the Implementation Regulations that the EPC came to be applied as it is currently. Consequently, the statement as cited (“... meaning that the legislator could not have had the intention to limit patentability of plant-related inventions to transgenic plants and processes of genetic modification.”) ignores the history of Art 53 EPC and insinuates a specific intention of the legislator for which there is no sufficient evidence.

3. Legal analysis: Does the Biotech Directive allow for patents on conventional breeding?

There are substantial reasons to assume that the legislator, when adopting Directive 98/44/EC, wanted to restrict patents on plant-related inventions to those that are derived from genetic engineering. First of all, there is no doubt that the overall purpose of Directive 98/44/EC was to allow patents in the area of biotechnology – its title is “Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions”. This view is also supported by the wording of the Directive. For example, recitals such as 52 and 53 of Directive 98/44/EC only discuss the compulsory cross-license in the field of exploitation of new plant characteristics resulting from genetic engineering.

Further indications can be derived from the history of the Directive. While the final version of Directive 98/44/EC was still under discussion (1995-1998), the European Patent Office (EPO) officially stopped granting of patents on plants and animals because of decision T356/93 made in 1995 (see above) as well as because of pending case T1054/96 (that led to decision G1/98).

Thus, Members of Parliament as well as experts from EU Member States and the Commission might well have been led to believe that the main purpose of the Directive was to pave the way only for plant-related inventions in the context of genetically engineered plants and animals. Indeed, the EU Directive acted as a game changer: As mentioned, G1/98 (Novartis) was decided after the Directive was adopted and became part of the new Implementation Regulations.

In addition, the wording of Article 4. 2, which is decisive in this context (*“Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety”*), can easily be derived from the technical background of genetic engineering i.e. working with isolated DNA that can be transferred even beyond the limits of species.

Doubts remain about whether Article 4.2 is meant to allow patents on plants and animals at all: In its original English version it speaks about “inventions which concern plants and animals” (which might be, for example, technical processes) which could be patentable, but does not state that plants and animals (which are not per se technical) can be patented. However, the exact meaning of this wording and possible divergent interpretations are not reflected in the *Report*.

No matter how these general questions regarding patentability of plants are viewed and interpreted, it can be assumed that when adopting Directive 98/44/EC, the legislator did indeed want to restrict patents on plant-related inventions to those that are derived from genetic engineering. At the same time, there is nothing to indicate that the legislator generally wanted to allow patents on plants and animals derived from essentially biological processes used in conventional breeding. It can be concluded, that all processes in conventional breeding as well as all products (plants, animals, seeds,

breeding material, breeding characteristics) derived thereof can be excluded from patentability without counteracting the intention of the legislator.

This point of view is supported by a resolution of the European Parliament adopted in May 2012⁹², which gave a different interpretation of the provisions of Directive 98/44/EC than that applied by the EPO. It says, the Parliament:

“3. Welcomes the decisions of the Enlarged Board of Appeal of the EPO in the so-called ‘broccoli’ (G 2/07) and ‘tomato’ (G 1/08) cases, dealing with the correct interpretation of the term ‘essentially biological processes for the production of plants (or animals)’ used in Directive 98/44/EC and the European Patent Convention to exclude such processes from patentability;

4. Calls on the EPO also to exclude from patenting products derived from conventional breeding and all conventional breeding methods, including SMART breeding (precision breeding) and breeding material used for conventional breeding; (...)

6. Welcomes the recent decision of the European Patent Office in the WARF case and of the European Court of Justice in the Brüstle case, as they appropriately interpret Directive 98/44/EC and give important indications on the so-called whole content approach; calls on the European Commission to draw the appropriate consequences from these decisions also in other relevant policy areas in order to bring EU policy in line with these decision. (...)”

4. Legal analysis: New legal questions in regard to plant varieties

The interpretation of Article 53(b) EPC was changed after Directive 98/44/EC was adopted. The Directive became part of the Implementation Regulations of the EPC in June 1999, at which point the EPO resumed granting patents on genetically engineered plants. The basis for these patents was mostly derived from Article 4.2 of the EU Directive 98/44:

“2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.”

In parallel, the Enlarged Board of Appeal at the EPO was also preparing the G 1/98 decision, that was published some months after the Directive was added to the Implementation Regulation. In its decision, the Enlarged Board of Appeal necessarily applied the logic behind Article 4.2 EU Directive 98/44.

The decision G1/98 concerned a genetically engineered plant produced by Novartis. Meanwhile, the EPO has extended this legal practice to conventional breeding. However, the criteria applied in G1/98 to define what is patentable cannot be applied to conventional breeding: In G1/98 plant varieties with characteristics that are based on a genotype (a specific combination of genetic conditions) were regarded as not patentable. On the other hand, plant characteristics, that are defined by a single DNA sequence and can be transferred to other plants by technical means, are regarded as being patentable (even if plant varieties fall within the scope of the patent). For

⁹² <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0202+0+DOC+XML+V0//EN>

example, a genetically engineered plant which has had a gene inserted into its genome in order to make it herbicide resistant would not be a plant variety as such plant grouping would not be defined by its whole genome, but by an individual characteristic linked to a specific defined and inserted DNA, i.e. the herbicide resistance.

But these criteria cannot be applied in the same manner to plants derived from conventional breeding as to genetically engineered plants: Many of the relevant plant characteristics described in patents on plants derived from conventional breeding, are not based on a single DNA sequence, but upon a combination of genetic conditions. For example, characteristics being described as Quantitative Trait Locus (QTL) vary in degree and can be attributed to polygenic effects. Thus, as a result the characteristics of these plants can be more accurately described as stemming from “a given genotype”, but not as being “defined by single DNA sequence”. Nevertheless, the EPO was granting several patents on plants with characteristics being described as Quantitative Trait Locus. Thus, in current EPO decision-making the distinction made between patentable and non-patentable plants has become completely indistinct.

In general, the criterion “if the technical feasibility of the invention is not confined to a particular plant or animal variety” (Article 4. 2 of Directive 98/44/EC) can hardly be applied in the field of conventional breeding. As has been explained, it can be assumed that “technical feasibility” is directed at processes for genetic engineering which enable the transfer of DNA sequences beyond the boundaries of species. In this context, the criterion has a specific meaning. But in conventional breeding any plant characteristics can be transmitted to any other varieties within the same species, just by further breeding. As a result, the criterion as given in Article 4.2. and applied by the EPO does not have a specific technical meaning and does not provide any legal clarity in the context of conventional breeding.

There is no doubt that in the context of conventional breeding the overlap between plant variety protection and patent protection is much stronger, and raises new legal and urgent questions in comparison to patents granted in the field of genetic engineering. In summary, if the provisions of Article 53(b) are applied to plants derived from conventional breeding in the same way as they are applied to genetically engineered plants, the prohibition of patenting plant varieties will become meaningless. In this case, patents also will also be granted on plants if

- they show characteristics that are based on a genotype and not only single DNA sequences
- they have characteristics that can be transferred easily to other plant varieties by crossing and selection and do not require technical means that can overcome the barrier between species.

It can be concluded, that in the context of conventional breeding, patents cannot be allowed if they overlap with plant variety protection. Furthermore, it can be assumed that such an interpretation of patent law can be made without counteracting the intention of the legislator of the EPC or Directive 98/44/EC. Conversely, such a clarification would be complementary to the second half of the sentence in Article 53(b) EPC that prohibits patents on essentially biological methods for breeding.

In this context, it should be noted that there is no legal basis for an argument saying that those plants that cannot be protected under the plant variety protection (PVP) system should have the

possibility to be protected under patent law. As stated in the EPC, plants that meet the criteria of Rule 26 (4) (a) – (c), EPC, have to be considered as plant varieties *irrespective of whether the conditions for the grant of a plant variety right are fully met*". (EPC, Rule 26 (4)) For example a "line" of plants that cannot be protected under PVP law can still fall under the exclusion of Article 53(b).

5. Legal analysis: Definition of essentially biological processes

If essentially biological processes are defined, the definition should be comprehensive, applicable in practice and flexible enough to encompass future development. From a technological point of view, two basic categories can be distinguished:

- Techniques that involve the transferal and insertion of externally prepared material into cells (such as transgenic plants, applications of nucleases, oligonucleotides and RNAi, genome editing) and
- Usage of the whole genome, cells or plants (such as MAS, random mutagenesis, protoplast fusion)

The applications in the second category can be considered as essentially biological from a scientific point of view because:

- These techniques make use of natural biological mechanisms such as the genome regulation in the plant cells.
- No biological material prepared outside the cells is used in these methods.
- The methods do not escape the mechanisms of heredity as developed during evolution.

In summary, the methods of the second category are mostly based on the plants' own biological potential and use natural genetic diversity, plasticity and variability. Using the second category as a definition for essentially biological processes within the meaning of patent law puts this definition into a meaningful scientific context, leaving enough flexibility to evolve further. The term "conventional breeding" could be used synonymously in this context.

This definition was proposed and discussed, but is not mentioned in the *Report*. Instead, it is stated that

"finding an exhaustive definition of 'essentially biological process' is probably an impossible task indeed, and maybe not even be worth trying."

In some passages the *Report* even mixes up techniques used in genetic engineering or genome editing (which are technical) with marker assisted breeding (which is regarded as 'essential biological'):

"Rapid technical development enabled the manipulation of conventional plants by genetic engineering techniques such as the use of molecular markers."

Further confusion is created by remarks which are not related to the relevant questions such as

“As explained, even genetically engineered products can be made by essentially biological processes.”

Further, table 2.2 introduces criteria derived from the Decision G2/07, that are too narrow to allow meaningful definition of essentially biological processes.

So in result, no meaningful definition of essentially biological processes is provided by the report. However, if no adequate definition is fixed, this can create a grey area, which might be used to extend the limits of patentability just by making case by case decisions. For example, the definition chosen in G2/07 and G1/08 applies to processes used in conventional breeding that consist of crossing and selection. Other steps in breeding (such as selection before crossing) and the introduction of new traits using methods such as random mutagenesis might be seen as being outside this definition although they are processes used in conventional (essentially biological) breeding.

In the *Report*, methods such as random mutagenesis and selection with crossing are not mentioned as falling within the grey areas around decision G2/07 and G1/08. As a result, the *Report* fails to mention crucial issues that have to be considered if a meaningful definition for essentially biological processes is to be found.

There are some very good reasons why the legislator should not leave the definition of essentially biological processes to the EPO and patent attorneys for case by case decisions, but instead should set clear limits of patentability. From this point of view, the following rules of interpretation/ for implementation of the relevant provisions of Directive 98/44/EC should be established so that:

1. Breeding processes that rely on the use of whole cells and/or crossing of whole genomes for introducing new traits into plants, and do not require the insertion of material prepared outside the cells are considered to be essentially biological.
2. Products or characteristics obtained, or might be obtained, by means of conventional breeding, all methods and steps used in conventional breeding, including e.g. SMART breeding (precision breeding) and breeding material used for conventional breeding are excluded from patentability under Art. 53(b) EPC.

6. Legal analysis: How to achieve more legal certainty

Analyses of EPO decision-making in recent years show that prohibitions established in patent law of patents on plant and animal varieties and essentially biological processes (Art 53(b) EPC) have been systematically eroded (Then & Tippe, 2014).

According to Then & Tippe (2014), it appears that the EPO has intentionally created an unprecedented situation full of legal absurdities: If all plants with specific characteristics and all processes for breeding are claimed, there is a high likelihood that the patent will be granted. The applicant only has to make sure that specific varieties or specific processes for essentially biological breeding are not claimed explicitly to be in accordance with the wording of the law. However, in essence, these patents cover plant varieties as well as products and processes of essentially biological processes for breeding.

As also mentioned in the *Report*, it is important to understand that the current case law does not even allow a clear distinction to be made between plants (and animals) derived from essentially biological processes and those derived from other methods. Consequently, the scope of patents granted on plants (or animals) derived from technical processes may encompass plants (or animals) obtained by essentially biological processes. Even though these are not deemed patentable, they may fall under the scope of a patent. This is a general problem that was also described in a report prepared on behalf of the German government in 2011 (Herdegen & Feindt, 2011). This report shows that if a patent on a plant is described by referring to a specific process, the scope of the patent is not limited to this process but covers all plants with the same characteristics. As a consequence, the scope of the patent could even cover plants or animals that existed before, but were previously not known to show the characteristics as described in the patent. This problem is also mentioned in the *Report*:

“a claim for a product covers all products falling under the scope of the claim, irrespective of the way the product was made. So even if a product obtained by an essentially biological process were in itself not patentable, if this product could be obtained using a technical process and could be patented, the scope of the product protection would also encompass the product obtained by different means.”

However, the *Report* does not consider the real range of possible solutions that might be used to strengthen the existing prohibitions in patent law. There is, in particular, no in-depth discussion relating to a change in the interpretation of the current provisions. For example, the following wording could be used to establish new rules for the interpretation of the Directive, and thereby achieve more legal certainty without changing its text:

- In assessing inventions and patent applications under the exclusion provisions of Art. 53 EPC the whole content of the specification of the patent application has to be considered in addition to the claims drafted for examination purposes. Exclusion of inventions from patenting under Art. 53 EPC shall not be circumvented by purposive drafting of the claims of patent applications. Technically unavoidable pre-process steps and technically unavoidable post-process steps and/or unavoidable post-process uses of the products shall constitute part of the invention, even if they are not explicitly disclosed in the specification and/or the claims of a patent application.
- The protection conferred by a patent shall not extend to plants and animals which contain the same or similar genetic information as a native trait or that can be obtained by means of an essentially biological process and which express the characteristics/ function described in the patent application.

A new interpretation of the Directive can be achieved either through political action taken by the Commission or the EU Member States, who can exercise political control through the Administrative Council of the EPO.

7. The context: Relevant drivers in current development

While in its chapter “background on plant breeding”, the role of companies that entered the business sector is explained to some extent, the *Report* as a whole very much gives the impression

that technological progress is the most relevant factor in current developments leading to an increasing number of plant patents.

In fact, the very first sentence of the summary introduces this narrow approach as the general underlying theme of the whole *Report*:

“The question which needs to be answered is whether technological developments in the last decade should lead the Commission to rethink the statutory and policy regime vis-à-vis plant related inventions.”

The *Report* only mentions, but does not emphasise the fact that a large number of the plant patents are based on techniques that have been used for many years, such as random mutagenesis, analysis of plant composition, marker-assisted selection, protoplast fusion and description of phenotypical characteristics. Thus, patents on such methods and characteristics derived thereof are introduced into the sector irrespective of new specific technological developments.

Further, the *Report* does not assess properly the overall costs of these technologies being introduced into plant breeding: Most of them are standard techniques (such as marker assisted selection) that are much more likely to reduce the cost than lead to a higher degree of investment.

The *Report* thus systematically under-represents the role of agrochemical companies that have entered the breeding sector in recent decades, and which follow a very different IP strategy than the traditional breeders, one primarily based on patents and no longer on plant variety protection.

In addition, the *Report* does not discuss to which extent the strategy behind those patents is driven by the intention to abuse patents law to misappropriate biological resources and hamper competition and innovation. The European Seeds Association (ESA) and national breeder associations (e.g. in the Netherlands and Germany) are voicing their concerns that access to biological resources needed for further breeding and safeguarding food security is largely restricted. In fact, current developments where there are an increasing number of patents in conventional breeding could have enormous negative consequences for innovation, competition and diversity within the traditional breeding sector in the EU. These patents not only restrict the freedom of single breeders to operate, but might well systematically hamper innovation and competition and therefore can become obstacle in establishing food security (see Louwaars et al., 2009; Feindt, 2010).

There is no doubt that patents on seed and plants are synergistically accelerating the concentration process in the breeding sector, giving more and more power to big corporations that can afford the costly system of patents and deal with its legal uncertainties. This problem is not sufficiently represented in the *Report* although it is to some extent laid out in the chapter on the background of plant breeding. The *Report* makes hardly any mention of the downstream consequences of this development for farmers, consumers, food producers, the agroecological systems and the adaption to climate change (see below).

In conclusion, it is important to state that new technological developments in plant breeding are not the main drivers in current developments that are leading to an increasing number of patents in conventional breeding. There has always been innovation within the plant breeding sector that could be considered as technical improvement. However, these innovations have so far not changed

the IP paradigm within the breeding sector, which is the plant variety protection system. Certainly, the *Report* does not make sufficiently clear that access to biological resources for further breeding should have a high priority for any political decision-making in this context.

8. The context: The impact on agriculture, food production and consumers

The *Report* does not sufficiently discuss the effects of patents granted on seeds, plants and harvest that go beyond the breeding business. Some aspects are mentioned in the chapter on “background on plant breeding”. But there are several aspects that have to be considered in this context:

- Since patents on food plants in many cases extend to the whole chain of food production, it is likely that this will impact farmers, processors, retailers and consumers.
- Furthermore, if access to biodiversity is hampered, this is not only a problem for the breeders. It will have downstream effects on growers and farmers, even if the scope of patents were restricted to the level of seed production. Furthermore, it seems to be inevitable that these effects, at some stage, will also have an impact on food producers and consumers and might affect overall food security.
- Possible consequences are also a reduction in agro-biodiversity and an endangering of the ecosystems attached to it.
- The adaptability of our food production systems which is necessary to react to the challenges of climate change can be affected negatively.

With an increasing number of patents on food plants, that is likely to evolve in parallel and synergistically with an increasing market concentration in the breeding sector, the potential negative impacts on the overall markets for food production and on agrobiodiversity are likely to increase.

The *Report* mentions the high number of plant varieties being registered at the Plant Variety Office (CPVO), but it fails to sufficiently describe an ongoing concentration process in the seed sector that endangers competition in seed market, the survival of traditional seed companies, and in the end the true choice for farmers and growers. Some companies that are attached to an IP strategy based on patents have already gained a fairly dominant position on the market. In 2013, the Commission presented a report on the structure of the EU seed market, which also gives an overview of the situation on the global seed market (Commission, 2013). According to this overview, international seed market concentration has increased dramatically in recent years. While in 2009, the biggest three companies had a market share of around 35 percent, by 2012 this figure had risen to 45 percent. At the same time, the market share of Monsanto, which is the biggest seed company, increased from 17.4 to 21.8 percent. There is no doubt that patents are increasingly promoting this process of concentration and putting the largest seed companies in a dominant market position. By buying up other breeding companies, the multinationals are also acquiring more varieties and genetic material from the breeders’ gene banks. If later on they bring their patented seeds on to the market, the genetic material the seeds contain can no longer be freely accessed by other breeders as it is now under the plant variety protection (PVP) system. Therefore, if patents on seeds are allowed, there will be a much greater effect on the concentration process than under PVP law. Acquisition of breeding companies, of breeding material and use of patent monopolies are all having a synergistic

effect on the process. In the end, as competition declines farmers, growers and consumers will be increasingly dependent on a few multinational corporations.

In the process for preparing the opinion, some Experts voiced the opinion that not much data would be available yet on the factual consequences for the downstream markets in Europe. However, waiting for these data to become available in larger quantities would substantially reduce the options for political decision-making that aims to prevent such negative consequences.

As a result, the *Report* does not inform the Commission properly about the possible negative consequences of an increasing number of patents being granted in the area of conventional breeding. Since these potential negative consequences are probably the most relevant issues from the perspective of a broader public, the *Report* suffers from substantial deficiencies.

It will be important to set adequate political priorities (see below) for the decision-making of the EU.

9. The context: Current political actions

There are a number of relevant political and public activities in this field that the Commission should be aware of in the context of Article 16(c) of Directive 98/44. Some of the informations given below are not mentioned in the *Report*:

- In a resolution brought forward by the European Parliament on 10 May 2012 on the patenting of essential biological processes, “the European Parliament calls on the EPO also to exclude from patenting products derived from conventional breeding and all conventional breeding methods, including SMART breeding (precision breeding) and breeding material used for conventional breeding.”⁹³
- More than two million people have signed the petition urging the Administrative Council of the European Patent Organisation “to close the loopholes that allow corporations to patent plant varieties and conventional breeding methods. Clear and effective safeguards and prohibitions are needed to protect consumers, farmers and breeders from the corporate takeover of our food chain”.⁹⁴
- A breeders’ exemption was introduced into the EU Unitary Patent to emphasise the importance of the PVP law and access to genetic resources in this context.
- In national patent legislation (such as in Germany and the Netherlands) some elements have already been introduced ascertaining that products derived from essentially biological breeding are non-patentable. Also France and Switzerland are excluding patents on plants and animals derived from conventional breeding just by interpretation of current law.
- In the coalition treaty of the current German government, a European-wide initiative was announced to stop patents on plants and animal derived from conventional breeding.

⁹³ www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0202+0+DOC+XML+V0//EN

⁹⁴ www.avaaz.org/en/monsanto_vs_mother_earth_loc/?slideshow

- In 2015, the French Institut National de la Propriété Industrielle published a statement contradicting the G2/12 and G2/13 decisions.⁹⁵
- The German Bundesrat in its 935 meeting in July 2015 voted for taking actions to correct the decision of the Enlarged Board of Appeal by change of the EU Patent Directive.⁹⁶
- In July 2015, the Dutch government took the G2/12 and G2/13 decisions to the EU AGRIFISH council, and started an initiative for a full breeders' exemption. In the protocol it is stated that "The Netherlands regretted this decision. Several Member States supported the position of the Netherlands delegation, considering that this could have an impact on food production and food security, blocking innovation."⁹⁷
- The Dutch government also announced an initiative during its Presidency of the Council of the European Union in first half of 2016.
- In August 2015, the government of Austria announced to become active against patents on plants and animals.⁹⁸

10. Conclusions: Setting the right priorities for further political action

The *Report* defines three abstract categories for further political initiatives of the Commission. But no criteria were given on how to set priorities in this field. There are specific interests in this context that could be highlighted. For example, from the perspective of professionals with a commercial interest in legal activities around patents, it is important that the patent system is expanded to increase the patent business. Furthermore, companies applying for patents on plants are interested in weakening the prohibitions in patent law to extend their patent monopolies and increase market power. However, from the perspective of a broader public, the interests of traditional breeders, farmers, food producers and consumers there are other priorities that have to be met:

- Breeders have a strong interest in maintaining access to biological diversity to ensure further innovation.
- Farmers need diversity in the seed market and reasonable prices. Some of them want to use seeds they have harvested themselves or own propagation material either to sow or carry out further propagation and/or breeding.
- From the perspective of food producers and consumers there is a need for affordable food that is healthy and diverse and produced in an environmental friendly way.
- From a global perspective, access to appropriate seeds, a high level of agrobiodiversity and regional adaptability of agriculture to actual needs and challenges (such as climate change)

⁹⁵ <http://www.inpi.fr/fr/l-inpi/actualites/actualites/article/non-brevetabilite-des-plant-es-et-des-animaux-obtenus-par-croisement6130.html?cHash=560a6fdd572f246862b9c810a9cc2d37>

⁹⁶ <http://www.bundesrat.de/SharedDocs/TO/935/to-node.html>

⁹⁷ www.consilium.europa.eu/de/meetings/agrifish/2015/07/13/

⁹⁸ www.bmvit.gv.at/presse/aktuell/nvm/2015/0813OTS0138.html

are a priority for food security and food sovereignty.

There are very good reasons to assume that excluding patents on plants and animals derived from conventional breeding will accord with the needs of (traditional) breeders, farmers, food producers and consumers. From the analysis that is available so far, these prohibitions in patent law will foster innovation, competition, a greater variety of seeds, reduce market concentration and enable more choice for farmers and consumers and in consequence will support food security.

Although the summary of the *Report* cites the International Licensing Platform (ILP) for plant breeding as a possible solution, it has to be acknowledged that this initiative, launched by private industry, does not provide legal certainty, only involves specific plant species and is not supported by several of the bigger companies. Thus, it is a platform that serves to highlight the need for effective mechanisms to access plant material needed for further breeding, but cannot in itself be regarded as a solution.

It also has to be acknowledged that, as evidenced by a recent initiative by the Dutch government requesting the introduction of a full breeders' exemption into patent law⁹⁹, the limited breeders' exemption is not generally regarded as being sufficient.

Thus the priority of the Commission should be to stop the current practice of patenting plants and animals. The first step should be to strengthen the existing prohibitions by careful interpretation of law. This step should include the following elements:

- Breeding processes that rely on the use of whole cells and/or crossing of whole genomes for introducing new traits into plants, and do not require the insertion of material prepared outside the cells should be considered to be essentially biological in the meaning of patent law.
- Products and / or characteristics obtained, or might be obtained, by means of conventional breeding, all methods and all steps used in conventional breeding, including e.g. SMART breeding (precision breeding) and breeding material used for conventional breeding is excluded from patenting under Art. 53(b) EPC.
- In assessing inventions and patent applications under the exclusion provisions of Art. 53 EPC the whole content of the specification of the patent application has to be considered in addition to the claims drafted for examination purposes. Exclusion of inventions from patenting under Art. 53 EPC shall not be circumvented by purposive drafting of the claims of patent applications. Technically unavoidable pre-process steps and technically unavoidable post-process steps and/or unavoidable post-process uses of the products shall constitute part of the invention, even if they are not explicitly disclosed in the specification and/or the claims of a patent application (see Dolder, 2007).
- The protection conferred by a patent cannot be extended to plants and animals which contain the same or a similar genetic information and/or exhibit plant characteristics as a native trait or that can be obtained by means of essentially biological processes.

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www.consilium.europa.eu/de/meetings/agrifish/2015/07/13/

A change in the interpretation of current patent law can also be achieved through political action taken by EU Member States through the Administrative Council of the EPO.

The next step could then be to reopen and amend Directive 98/44/EC to exclude all breeding processes and breeding material, plant and animal characteristics, gene sequences, plants and animals, as well as food derived thereof from patentability.

A third step should aim to achieve a better incorporation of public interest within patent law, by for example introducing independent jurisdiction and strengthening political control of European patents.

There may well be some extra steps that could be taken to achieve a resolution to some of the problems. In this regard, minority positions are supported (as mentioned in the *Report*) that include activities concerning a full breeders' exemption and / or licence of right. In regard to a full breeders' exemption it should be acknowledged that it could be introduced into EU law without reopening the Directive completely. Therefore, taking legal measures should be feasible within a relatively short period of time.

Since plants and animals are essential resources for the provision of our daily food, we should not give private companies the power to gain control of breeding and the downstream process of food production. Contrary to the majority opinion of the Expert Group, taking no political action at all can definitely not be an option.

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Annex A4.

Dissenting Opinion

expressing disagreement with the conclusions of the Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering concerning a number of points with regard to patent protection for plant-related inventions

By Szonja Csörgő

The present document expresses the opinion of an expert representing the European plant breeding sector which disagrees on a number of points with the conclusions of the Report reached by a majority opinion of the Experts. Before presenting the background and the arguments behind the dissenting opinion it has to be noted first that the process of the Commission Expert Group provided an effective platform for discussion and exchange of views and allowed the author of the present opinion to present the problems and arguments of the European plant breeding sector. Nevertheless, on many issues a majority of the Experts coming from a different background more related to patents did not consider the plant-related issues being of such an importance that would warrant any action. In this respect it is interesting to note that the link between food security and the impact of patents on plant-related inventions on access to genetic resources was considered by the majority of the Experts as not relevant for the discussion and the problematic issues as presented by the breeding sector were often regarded as a fear or speculation as the practical impact of patents on the availability of genetic material for breeding is not yet clearly quantifiable. Since the European plant breeding sector clearly is of the view that ignoring the impact on food security and questioning the dimension of the problems at issue renders the whole approach erroneous, it is necessary to express a dissenting view on a number of matters discussed in the Report.

Introduction of the matter at stake

The Report presents in a rather comprehensive manner what plant breeding is and how it works,¹⁰⁰ therefore the present introduction focuses rather on the practical problems from the perspective of breeders and the legislative background.

As described also in the Report, plant breeding is the science of recombining the genetics of already existing plant varieties with the purpose of creating something new. In other words, a new plant variety is always based on already existing ones and can only be created by the physical use of plants. Therefore, access to existing plants and their genetics is the basis of plant breeding since those constitute the starting material of breeding work. Furthermore, it has to be underlined that throughout a breeding program thousands of plants have to be screened in order to identify interesting traits. The aim of a plant breeder is always to obtain the best possible combination of genetics responding to the determined breeding goals which implies that access to the widest possible genetic variability is key for a successful breeding program. It was questioned in the Expert Group whether breeding was impossible if access to certain material was impeded by patents or could the breeder work also with less material. Certainly, breeders can still work with less material

¹⁰⁰ See pages 4-5 of the Report.

however the real question is whether it is desirable that breeders work with less and whether such restrictions should not rather be categorically refused as a matter of principle.

Breeding programs are not run in an *ad hoc* manner but are aimed at carefully determined breeding goals which are themselves driven by farmer, grower and consumer demand and to a large extent by various environmental and societal challenges. The importance of such challenges should not be underestimated when talking about plant breeding as they are key in the determination of breeding goals. For example in case the climatic conditions of a certain area change because there is less rain than before then the characteristics of cultivated plants also have to be adapted to the new climatic conditions otherwise yields will drop which will immediately have an impact on food production. Farmers need varieties which are adapted to the (changing) climatic conditions otherwise their businesses are threatened, and as said, food production may also suffer. In today's world, with the always growing population it must be ensured that there is always enough, good quality food available. It may happen any time that there are sudden diseases popping up somewhere destroying the totality of a very important crop for a country or a region which requires quick and efficient reaction. To illustrate such a situation one can think of the Irish potato blight. Breeders all around the world are mutually dependent on each other since a sudden need for germplasm from the other side of the world may occur anywhere at any time. Therefore access to all genetic material for further breeding is a basic principle in plant breeding since the lack of such access may have very serious consequences and in this sector which is crucial for food production and thus for food security it is simply not affordable not to have access to all possible genetic material for further breeding.

As regards the legal background, the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights of 1994 (TRIPs) provides certain criteria concerning the availability, scope and use of Intellectual Property Rights and requires Members to set up a legal framework complying with such criteria. Regarding the protection of plant varieties, Article 27(3)(b) of the TRIPs Agreement provides for a choice between patents, an effective *sui generis* protection system or a combination thereof.

Since decades European plant breeders have been benefitting from the *sui generis* intellectual property system of plant breeders' rights (PBR) based on the UPOV Convention which provides effective IP protection for new plant varieties as such and fits the specific nature and needs of the breeding industry. This system provides for effective protection of plant varieties in order to obtain return on investment and – at the same time - it guarantees the continuous flow of improved plant varieties by safeguarding access to genetic variability through the so-called breeders' exemption.

This (full) breeders' exemption is a key cornerstone of the PBR system. As explained also in the Report (chapter 5), it provides that all varieties protected by PBR can be used for further breeding and the resulting variety can be commercialized without any obligation towards the PBR holder of the variety that was used to develop the new variety. This feature has always been relied upon by breeders for further improvement on each other's varieties and boosted innovation in plant breeding.

As explained also in the Report, plant varieties as such as well as essentially biological processes for the production of plants are excluded from patentability. However, due to case law of the Enlarged Board of Appeal of the European Patent Office and certain provisions of Directive 98/44/EC while in

theory plant varieties as such are excluded from patent protection, in practice – as a result of the specific nature of plant-related patents and of the abovementioned case law – plant varieties often fall under the scope of certain patents. As the current European patent system does not provide for a breeders' exemption this blocks access to biological material for further breeding which material otherwise would be free for such purposes under PBR.

As explained above access to genetic material is the basis of plant breeding and to make sure that breeding work is not jeopardized by patents on plant-related inventions it is necessary to ensure the access to genetic variability for the development of new, improved plant varieties. Therefore free access to all plant genetic material for further breeding has to be safeguarded. This principle should be guiding and should constitute the basis for discussion when considering if and what actions are needed to address the situation.

Products obtained by essentially biological processes

Essentially biological processes for the production of plants are excluded from patent protection. A clarification of the concept of essentially biological processes was provided in the Tomato and Broccoli decisions of the Enlarged Board of Appeal where it was also reiterated that the aim of this exclusion is to keep breeding methods based on crossing and selection of whole genomes free from any protection since this is the essence, the daily work of breeders and cannot constitute subject of protection. Since under patent law product protection is absolute, if a patent is granted on a plant obtained by essentially biological process that means that the patent is infringed if the product is produced in whatever way, including by an essentially biological process. In other words, it means that – even though excluded from patent protection – the essentially biological process for the production of the patented plant cannot be performed as it would immediately amount to patent infringement.¹⁰¹ In order to keep this exclusion effective and to make sure that breeders can indeed meaningfully practice the essence of their work without risking any patent infringement, products obtained by essentially biological processes should also be excluded from patent protection. In practice this means that a plant or plant trait should be patentable only if it is produced by a process which is not based on crossing and selection. The decisive question for the patentability of biological material should therefore be the process which is used for the production of the biological material.

As noted also in the Report, the national patent laws of Germany and the Netherlands explicitly exclude products obtained by essentially biological processes from patentability.¹⁰² While it is true that two out of 28 Member States is a rather small minority, it also has to be underlined that Germany and the Netherlands are two very important countries in the European plant breeding sector. Further on, both countries are bound both by the EPC and the Biotech Directive therefore excluding products obtained by essentially biological processes does not seem to be contrary to the rest of the provisions of either the EPC or the Biotech Directive. Regarding the provisions of the EPC the recent decisions (G2/12 and G2/13) of the Enlarged Board of Appeal of the EPO state that an extensive interpretation of the process exclusion in the EPC is not possible. It would be desirable if the Commission could issue a statement clarifying that under the Biotech Directive such extensive interpretation was not problematic but on the contrary, is rather necessary for the sake of consistency and for ensuring the effectiveness of the process exclusion. It is also interesting to note

¹⁰¹ See page 31 of the Report

¹⁰² See page 33 of the Report.

that at the Seminar on the Interface between Patents and Plant Variety Rights organised by the Community Plant Variety Office in Brussels on 24 June 2015, it was announced that the French government together with some Members of Parliament is also working on amendments of the Biodiversity Law aiming at a proper balance between plant breeders' rights and patents (i.e. an exclusion of plants of essentially biological processes from patentability).

It was discussed in the Expert Group and is also contemplated in the Report¹⁰³ whether excluding the plants obtained by essentially biological processes would in itself be enough to keep the exclusion meaningful. As also explained in the Report the answer to this question is negative since patent protection may still be granted on technically produced plants on which the patent protection is equally absolute, i.e. encompasses the production of the plant by any means, including by an essentially biological process.¹⁰⁴ Therefore, in order to make sure that the practice of essentially biological processes for the production of plants remains indeed free of private rights as intended by the legislator when putting in place the process exclusion, it should be ensured that the effect of patents granted on plant-related inventions does not extend to products having the same properties as the patented material but produced independently, without the use of the patented material, and by a breeding process based on crossing and selection.¹⁰⁵

Breeders' exemption

As explained thoroughly in the Report as well as in the introduction here above, access to genetic material for further breeding is the *conditio sine qua non* of plant breeding. Since the very existence of plant breeding such access has been guaranteed and has been relied on by all breeders. When the UPOV Convention was adopted with the aim of providing IP protection for plant varieties the free access has been institutionalized via the breeders' exemption which is a key element in plant variety protection as it allows for speedy innovation in plant breeding. In such a sector where the process to arrive to a new plant variety is fairly long whereas the challenges to respond to are many and are always changing it is crucial that breeders can profit from each others' achievements since like this a lot of time and efforts can be saved. If no similar exemption is provided for in patent laws all genetic material covered by the scope of a patent becomes unavailable for further breeding unless a license is obtained from the patent holder. It has been argued in the Expert Group by several Experts that in fact patent protection does not block access to material covered by the scope of a patent since a license can always be sought¹⁰⁶. At first sight this seems to be a reasonable argument indeed however it is also clear that a patent holder is not obliged to give a license, he may keep exploitation of his invention exclusively to himself. Secondly, although it is a purely economic argument, it cannot be ignored that not all breeders can afford applying for licenses due to the high costs involved in the negotiations and the lack of expertise in the field of patents. One may think that in principle this is not a problem since such players will then disappear from the market which is a natural phenomenon of market economy. In fact, concentration in the breeding sector has already been going on for a couple of years but it has to be underlined that in a sector which has a key role in ensuring food security over the world it is not desirable to have a high degree of concentration. On

¹⁰³ See pages 32-33 of the Report.

¹⁰⁴ See page 33 of the Report

¹⁰⁵ For more details on how such provision could work in practice reference is made to the discussion described in the Report (pages 37-38).

¹⁰⁶ See page 45 of the Report

the contrary, a diverse sector is highly important. Last but not least, as explained in the introduction of the present dissenting opinion access to all genetic material for further breeding is the basis of plant breeding and not having access to one or the other material is not affordable since responses to ever new challenges have to be found constantly and as soon as possible. A limited breeders' exemption, allowing such access unconditionally and without delay is therefore a must as a matter of principle.

It was also argued by several Experts in the Expert Group that adopting an exemption for a specific field of technology is not desirable and/or justified since many other sectors can find their own specificities and the argument that plants are different was dismissed. Nevertheless, the author of the present dissenting opinion is of the view that plants are indeed different and they deserve a differentiated treatment. It can already be seen in the TRIPs Agreement itself that plants and plant varieties are treated differently from other fields, TRIPs even allows Contracting Parties to completely exclude plants from patentability. The fact that there is a specific *sui generis* IP right for plant varieties also confirms that there is something specific about the field of plants and plant breeding. Also in the field of biodiversity laws plant genetic resources are treated differently from other genetic resources and are, in principle, not governed by the CBD but by a specific international instrument, the FAO International Treaty for Plant Genetic Resources for Food and Agriculture (the Treaty). The reason for this specific treatment of plant varieties and plant genetic material comes down to the issue of access again.

Access in the CBD is organized in a bilateral manner where provider and recipient negotiate with each other the conditions and modalities of access (and benefit-sharing). This bilateral arrangement for access is not convenient for plant genetic resources since in plant breeding access has to be quick, guaranteed and available to all for further breeding. For this reason a specific international access and benefit-sharing instrument has been adopted for plant genetic resources for food and agriculture under the aegis of the FAO. In the Treaty access to plant genetic resources is organized in a multilateral system which, in fact, works as a basket where Contracting Parties put in their genetic resources and from which everybody can access any genetic resource under the same terms and conditions. This way of facilitated access for the purpose of breeding fits perfectly well with the specificities and needs of plant breeding, i.e. with the need to have access to all genetic resources for further breeding. Since access to plant genetic material for further breeding is safeguarded in all legislation related to plant varieties, it is therefore very well justified to treat plant genetic material and plant breeding different from other fields of technology and to introduce a specific exemption into patent law with the view of safeguarding access.

As mentioned in the Report and as was discussed in the Expert Group the Unified Patent Court Agreement in its Article 27(c) provides for a limited breeders' exemption. The provision in the UPC Agreement is undoubtedly a very important one and is a natural confirmation of the trend that has been started in several national patent laws. However, as already stated several times before, access to all genetic material has to be ensured for further breeding, and in this respect the UPC Agreement has several shortcomings. First of all, it does not cover all patents, national patents are not in its scope at all while such national patents may still be relevant in the field of plant breeding; second, not all Member States participate in the system; and third, the UPC Agreement may never enter into force. The author of the present opinion, as just explained, is of the view that in order to safeguard access complete harmonization is needed which cannot be reached via the UPC Agreement even if

one is very optimistic and supposes that one day all Member States join and the Agreement enters into force. Therefore, legislative action (outside Directive 98/44) ensuring the introduction of an EU-wide limited breeders' exemption is desired.

Via the combination of all the elements presented in the present dissenting opinion it could be achieved that breeding work is not disturbed by the patent system. For that however some actions by the European Commission would be necessary with regard to the legal framework. Therefore, on the conclusions and recommendations to chapters 3, 4 and 5 the author of the present opinion respectfully dissents from the majority view taken by the Expert Group. The essence of the present dissenting opinion is supported by Pere Puigdomènech on all chapters referred to above and by Anselm Kamperman Sanders and Gautier Pereira on chapter 5.

Annex A5. Dissenting Opinion ex Chapter 5 Plant Report

Authored by Sven Bostyn.

The essence of this Opinion is supported by Robin Jacob, Sisko Knuth-Lehtola, Clara Sattler De Sousa e Brito, Joe Taormino and Peter Würtz Lindum.

Some members of the Expert Group members have expressed themselves in favour of the introduction of a limited breeders' exemption, even though the reasons for doing so do not seem to have been informed by a satisfactory critical analysis, at least in the view of the present author.

What is presented here is a qualified dissenting opinion or even perhaps more of a reflection in relation to Chapter 5, Breeders' exemption. The dissenting opinion is qualified for a number of reasons.

Firstly, the present author is aware of the statutory development which has taken place and is still taking place, where a number of Member States have already introduced a limited breeders' exemption. Furthermore, the Agreement on a Unified Patent Court has equally introduced a limited breeders' exemption in Article 27(c).

Secondly, the present author is also sensitive to most of the arguments that have been brought forward in support of a limited breeders' exemption, for which see the Report.

However, for the reasons that follow, it is believed that supporting the introduction of a limited breeders' exemption is likely to have potentially such negative effects on the integrity of the patent system that it is advisable to oppose such introduction. That belief is additionally informed by the fact that the breeders' exemption is only one element in an entire package that proponents of such introduction present to carve out a world where breeders would not be negatively influenced by patents in their daily business, which is likely to imply an even further limitation of the patent system, and thus have even further reaching effects on the integrity of the patent system.

By "integrity of the patent system", the present author does not aim at placing the patent system in isolation from wider considerations such as innovation policy and the co-existence of mutually supportive IP systems. However, the present author has not seen convincing evidence in the Report that the choice for a limited breeders' exemption is in fact supportive of such wider considerations. The present author is not negative towards any co-existence, but in the view of the author, that is exactly the issue. The (limited) breeders' exemption introduces into the patent system a "foreign body", a concept not known to the patent system, and the policy reasons for doing so, even though the present author understands them perfectly, do not justify a fundamental departure from fundamental principles of patent law, as the Report does not contain convincing evidence that such departure would be justified only for plant related inventions. Indeed, as will be demonstrated in what follows, many sectors of technology could invoke similar demands, and one must ask the question whether that is the direction we want the patent system to go into, in respect of wider considerations such as innovation policy. This dissenting opinion is not the place to have this debate, but it is the belief of the present author that this debate should be had before one introduces a concept foreign to the patent system for one sector of technology instead of afterwards. The Report

does not contain evidence of such debate and hence of a proper justification for introducing a limited breeders' exemption.

Even though some will categorically deny that there is a relationship between the introduction of the concept of "essentially derived variety" in the plant variety right system (PVR system)¹⁰⁷ and the lack of enforcement possibilities due to the full breeders' exemption available under PVR systems, the present author believes that a certain degree of dissatisfaction of some users of the PVR system with the said lack of enforceability of plant variety rights due to the full breeders' exemption has led to the introduction of the aforementioned concept of "essentially derived varieties". The said concept thus in effect limits the scope of the full breeders' exemption by allowing the plant variety right holder to extend his/her rights to plant varieties which are deemed to be "essentially derived" from the protected variety. That in effect implies that at least for such essentially derived varieties, a full breeders' exemption will not be applicable. Even though the above argument is relating to the full breeders' exemption, the present author believes that it symbolises a wider dissatisfaction with the concept of breeders' exemption and the wider implications of lack of exclusivity, the latter being involuntary.

Importantly, one cannot deny that the underlying rationale of both the PVR system and the patent system are quite different, which makes it inherently risky to perform legal transplants. Originally, the PVR system was devised to provide some form of IP protection for the investment made in developing new varieties, which was a welcome compensation for the effort put in plant variety innovation. Investment in developing new varieties was in the early days less a matter of financial investment as it was a matter of time consuming labour. Consequently, the focus of the PVR system has traditionally always been more on having strict criteria for protection and a good examination of those criteria with a view to obtain stable varieties which would be beneficial to the relevant industry, than it was on scope of protection and hence the strength of the exclusive right.

Also, in view of the specifics of the PVR system that protects a certain commercial variety (i.e. a product at the end of the development chain) and not an abstract technology such as is the case with the patent system, having a breeders' exemption in the PVR system would not have a devastating effect on PVR right holders, as there was a considerable lead time advantage given to the PVR right holder.¹⁰⁸ Under the "traditional" PVR system, it also took many years before a

¹⁰⁷ Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, Article 13(5): "5. The provisions of paragraphs 1 to 4 shall also apply in relation to: (a) varieties which are essentially derived from the variety in respect of which the Community plant variety right has been granted, where this variety is not itself an essentially derived variety; [...]". And See Article 13(6): "6. For the purposes of paragraph 5 (a), a variety shall be deemed to be essentially derived from another variety, referred to hereinafter as 'the initial variety' when: (a) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety; (b) it is distinct in accordance with the provisions of Article 7 from the initial variety; and (c) except for the differences which result from the act of derivation, it conforms essentially to the initial variety in the expression of the characteristics that results from the genotype or combination of genotypes of the initial variety."

¹⁰⁸ The PVR system is subject to a considerable number of very time consuming field trials, de facto giving the right holder a lead time advantage, as a third party breeder would have to go through a similar time consuming exercise before he could ever bring his new variety on the market. Furthermore, the PVR

competing breeder would be able to come on the market with a new variety developed on the basis of the protected variety by invoking the breeders' exemption. The aforementioned lead time advantage present in the PVR system is not available in the patent system, as patents protect a technology as such, and not only a specific commercial embodiment. Once the patent application has been published (which is in principle 18 months after filing date), competitors can start using the technology with a view to make their own innovations, which will be many years before any commercial embodiment is brought on the market by the patent holder.

That brings us to a related point, which is that the PVR system protects a final product and the PVR is obtained once the final commercial variety is virtually ready for marketing, which means that relatively soon after obtaining the PVR (taking into account regulatory requirements which may cause further delays for all breeders alike), a commercial product will be capable of entering the market. That is very different from patent protection, which protects a technology and is as such more remotely linked to a commercial product, the latter often requiring years of further research to obtain after the patent application has been filed. Allowing third parties to use freely the patented technology for breeding purposes makes those third parties direct competitors to the patent holder who might not have a product on the market for years after the patent application has been filed. It is theoretically possible that both patent applicant and competitor, the latter using the patented material under a breeders' exemption, come on the market with a commercial product at the same time (even though admittedly the limited breeders' exemption which is at issue here does not allow third parties to market the new innovation without consent of the patent holder, but that does not distract from the gist of the point), something which would be inconceivable under the PVR system, for the reasons mentioned above. That implies that introducing a limited breeders' exemption immediately interferes with patent protection at its heart, while this is not the case for PVR systems. Or put in other words, the breeders' exemption has been devised with the specificities of the PVR system in mind, and has not been devised for other intellectual property rights. The present author is pleased to see that the Report has adopted at least part of the above analysis in its text.

One of the more prominent arguments that has been invoked to support introducing at least a limited breeders' exemption has been that the "sector" has already an alternative system in place, i.e. PVR's, to protect the fruits of plant breeding labour and that this PVR system does provide for a breeders' exemption. The patent system would interfere with that already long lasting system. There is some merit in that argument, but only some. There are other sectors of technology where alternative systems existed before patent protection entered the scene, and there is no evidence in these other sectors that the sudden application of the patent system has wiped most players out of that technology market or indeed has led to a technological stand still. A good example is software. Traditionally protected by copyright, patent protection for software related inventions entered the scene in the late 1970's early 1980's. Copyright protection is rather limited in scope compared to patent protection and furthermore protects different aspects of the software, copyright protecting the source code and some of the user interface, whilst patent protection will protect the underlying technical effect and the functionality. Consequently, with copyright protection only, there is a substantially reduced risk of committing an infringement by developing competing software with similar functionality as long as the source code is different and the user interface would not be

system protects the commercial variety, and competitors would have to start analysing and "reverse engineering" the protected variety once it has entered the market, hence the lead time advantage.

identical. Under patent protection, the technical effect and the functionality will be protected, thus creating a more extensive scope of protection, and hence implying a higher risk for infringement. Additionally, the patent system does not have an independent creation exception which the copyright system has. The software industry has never before thrived as much as today, despite the fact that the patent system has entered the software scene notwithstanding a tradition without patents. In conclusion, invoking the argument that a traditional system has been in place for a long time which provides certain rights which might be at risk under a different legal system is no reason for the hasty introduction of a legal concept existing under that older traditional system into the patent system, which introduction might and will in most cases not fit well within the patent system.

Another most prevalent argument in the context of the breeders' exemption is that in the absence of such exemption, breeders will be forced out of the market and that could hypothetically and potentially have negative effects on food security. This is a typical "scare" argument, and there has been not one single element of evidence provided that there is a serious risk of this to happen. Fear is always a bad advisor and should rarely if ever inform a legislature in creating or amending intellectual property right systems. There are many sectors of technology where similar arguments could be invoked, thus taking away the often claimed "special case" argument of plant breeders.

Software is today so intrinsically linked to all aspects of our daily life that one could easily claim that all software has to be available to everyone for further development without being burdened with the risk of infringement issues, which is not possible under the current state of patent law, as such approach would not fall within the confines of the research exemption, at least in most Member States. The present author has not been able to discern a wide support for introducing such far reaching exemption for software related inventions.

There is a public interest in getting access to the best possible medicines, which implies that any means to speed up R&D in the pharmaceutical sector should be supported. One could easily argue that, by creating a similar type of exemption as the breeders' exemption for pharmaceuticals, which would amount to an extended research exemption, it is more likely that better and/or more medicines would become available more quickly, as more players would be able to compete in the R&D field, whether on the basis of one's own research or on the basis of the research and products developed by competitors. Society at large would allegedly benefit from such "shared R&D" as it will organise more competition in research. Also here, the present author has not been able to discern a wide support for introducing such far reaching exemption for pharmaceutical inventions, as there are clearly also drawbacks to creating such far reaching exemptions, on which further below.

In a world with depleting fossil fuel supply and raising carbon dioxide levels, alternative energy supply through solar, wind, biomass, hydropower, geothermal energy etc. is not only relevant but most likely absolutely essential for the coming generations. It can hence equally be argued that, in view of the crucial role of energy in our daily lives and in the economy at large, such technology should always be available for further development, so as to ensure that the best possible technologies at the speediest possible pace are developed to ensure that life on our planet remains sustainable. That goal could easily imply the introduction of a type of widened research exemption, very similar to the breeders' exemption. Once again, the present author has not been able to discern a wide support for introducing such far reaching exemption for alternative energy related inventions.

In conclusion, it is clear from the above that it is very easy to make the case for quite a substantial number of technological developments to limit patent protection in favour of ensuring wider access to such technologies and an unhindered use of those protected technologies for further (competing) development. A fundamental question then becomes whether the integrity of the patent system can be maintained, as the substantial investments in developing such technologies will likely become unrecoverable as a consequence of such broadened access and unhindered use of those protected technologies for further (competing) development. This may easily have a negative effect on technological innovation, the goal that is by some invoked as the reason for introducing breeders' exemptions or extended research exemptions alike. Indeed, why would someone invest considerable sums of money if the forecast is that third parties will use the protected technology for the development of (competing) products and technology unhindered by any risk for an infringement claim? That could very well be the beginning of the end of the patent system as we know it today, as it fundamentally interferes with the *quid pro quo* principle underlying the patent system and hence damages its integrity. As said earlier, the present author does not aim at placing the patent system in isolation from wider considerations such as innovation policy and the co-existence of mutually supportive IP systems. However, the present author has not seen convincing evidence in the Report that the choice for a limited breeders' exemption is in fact supportive of such wider considerations.

The (limited) breeders' exemption introduces into the patent system a "foreign body", a concept not known to the patent system, and the policy reasons for doing so, even though the present author understands them perfectly, do not justify in the view of the present author a fundamental departure from fundamental principles of patent law, as the Report does not contain convincing evidence that such departure would be justified only for plant related inventions. As has been demonstrated, many sectors of technology could invoke similar demands, and one has to ask the question whether that is the direction we want the patent system to go into, in respect of wider considerations such as innovation policy. This dissenting opinion is not the place to have this debate, but it is the belief of the present author that this debate should be had before one introduces a concept foreign to the patent system for one sector of technology instead of afterwards. The Report does not contain evidence of such debate and hence of a proper justification for introducing a limited breeders' exemption.

Summarising, introducing a breeders' exemption in patent law is not only an undesirable and unwise legal transplant between two areas of the law which are quite separated from each other and which have different requirements and effects, the fact that it is based on a tradition is as such not a good reason for incorporating it in another system, in this case the patent system. Furthermore, the omnipresent argument that plant breeding deserves a special regime as it relates to such a fundamental and essential element of our life is as such not entirely convincing, as in today's world, the same could be said about software, drug development and innovation in alternative energy supply, for which no exemptions exist, and for which such introduction no wide claims have been made.

For all the reasons mentioned above, I respectfully dissent from the view taken by my learned colleagues to support the introduction of a limited breeders' exemption.

B. Subreport of the group on the patentability of human stem cells

In December 2013, the European Commission set up an Expert Group in order to assist the Commission in preparing a report on the development and implications of patent law in the field of biotechnology and genetic engineering.

The main observations and conclusions of the sub-group working on the evaluation of the patentability of “human stem cells” have been included in the present preliminary report after taking into consideration the working methods and the mapping paper of the Expert Group.

This report does not intend to be exhaustive, and must be considered as a working document for DG GROW to prepare its own recommendations. It does not have any legal value, and does not represent any individual position of the Experts, nor any speakers or position of the Commission itself and its representatives.

It should be stressed that ethical considerations do not fall within the mandate of the group, because these are within the remit of the work of the Commission's European Group of Ethics in Science and New Technologies.

1. An overview of the relevant technology

The last decade has seen tremendous development with respect to biomedical applications of human stem cells. In particular, the field of tissue-specific, adult stem cells has been complemented by the advent of human embryonic stem (ES) cells and human induced pluripotent stem (iPS) cells.

A Stem cell¹⁰⁹ shall mean an undifferentiated cell – i.e. a cell that has not yet developed into a specialized cell type. The two main characteristics of a stem cell are (i) the capacity to renew itself and to physiologically divide indefinitely and; (ii) the ability to differentiate to yield some or all of the major specialized cell types of the tissue or organ.

Adult stem cells are typically found in tissues with high turnover rates and regenerative potential such as e.g. bone marrow, skin, intestinal epithelium and others. *In situ*, adult stem cells enable these tissues to constantly replace organ-specific cells. Isolated and propagated *in vitro*, they can serve as a valuable source of donor cells for transplantation and other biomedical applications. For example, bone marrow cells have been applied clinically for many years to reconstitute the hematopoietic system in cancer patients; skin-derived stem cells can be used to grow skin-like tissue fragments for the treatment of burn victims, and limbal stem cells serve as autologous source for the treatment of severe cornea defects. It has been shown that some somatic cells can be reprogrammed to other cell types.¹¹⁰ Typically, adult tissue-specific stem cells will only give rise to cells of their organ of origin. This leaves a void for those tissues and organs, which lack a significant endogenous regeneration potential such as, e.g., nervous system, heart and insulin-producing cells. The advent of *in vitro* cultured **human ES cells** has provided prospects to overcome this

¹⁰⁹ National Institute of Health (NIH), definition accessed on January 2015 at <http://stemcells.nih.gov/info/basics/pages/basics1.aspx>

¹¹⁰ Xu, J. et al. (2015), Direct Lineage Reprogramming: Strategies, Mechanisms, and Applications, *Cell stem cell* 16:119–34.

limitation¹¹¹. Derived from the embryo in its earliest post-fertilization stages, ES cells self-renew extensively and are competent to generate cells of all tissues and organs, a property referred to as *pluripotency*. Since the first description of human ES cells in 1998, numerous protocols have been described, which enable the generation of various tissue-specific cells of all three germ layers including biomedically highly relevant cell types such as neurons and retinal cells, heart and insulin-producing cells, hepatocytes and many others. Translation into medical applications is progressing with first clinical studies being undertaken for ES cell-based treatment of age-related macular degeneration and spinal cord injury; first applications for cell replacement in Parkinson's disease are in preparation.

In 2007, Shinya Yamanaka demonstrated that human pluripotent stem cells with biological properties equivalent to those of ES cells can be generated by transcription factor-based reprogramming of adult skin fibroblasts¹¹². These **induced pluripotent stem (iPS)** cells provide the additional advantage that they can be derived in an autologous manner from the affected patient, thereby bypassing the risk of transplant rejection. In addition, iPS cells have developed into a promising tool for modelling diseases and developing pharmaceutical compounds directly in disease- and patient-specific cells.

Both ES and iPS cells are *pluripotent*, i.e. capable of generating derivatives of all three germ layers. They are, however, on their own unable to generate a developing organism, which distinguishes them from the *totipotent* embryo and its first stages of cell division.

A common route for conventional generation of human ES cells is to propagate surplus embryos donated from IVF procedure (with informed consent obtained from the donor couples) in cell culture until they reach the blastocyst stage. Under appropriate conditions, cells of the inner cell mass of the blastocyst can be induced to proliferate, thereby giving rise to stable cell lines termed embryonic stem (ES) cells. As this standard route for ES cell generation implies destruction of the blastocyst, it has ignited a plethora of ethical and legal debates.

In the wake of these controversies and in light of other advances in the field, stem cell scientists have come up with a number of alternative ways for deriving human ES cells¹¹³:

1. Derivation of ES cells without destruction of the embryo

This route is based on the isolation of single blastomeres from the 8 cell-stage embryo. The blastomeres are then propagated to generate pluripotent stem cells lines. Biopsied embryos were shown to be able to continue their development to the blastocyst stage.¹¹⁴

¹¹¹ Thomson, J.A. et al. (1998), Embryonic stem cell lines derived from human blastocysts, *Science* 282:1145-47

¹¹² Takahashi, K. et al. (2007), Induction of pluripotent stem cells from adult human fibroblasts by defined factors, *Cell* 131:861-72

¹¹³ Gavrillov S. et al. (2009), Alternative strategies for the derivation of human embryonic stem cell lines and the role of dead embryos, *Current Stem Cell Research & Therapy* 4, 81-86. - See Fig.1 p. 82 – as shown in Annex I.

¹¹⁴ Chung, Y. et al. (2008), Human embryonic stem cell lines generated without embryo destruction, *Cell Stem Cell* 113–117; strong scepticism is expressed in dissenting opinion.

2. Derivation of ES cells from irreversibly arrested human embryos

Several studies have shown that IVF-derived embryos, which have ceased their *in vitro* development can be used as donor source for the generation of ES cells.¹¹⁵

3. Generation of ES cells via somatic cell nuclear transfer (SCNT)

This route exploits the fact that diploid nuclei from adult tissue transferred into enucleated unfertilized oocytes can be reprogrammed by the latter and initiate embryonic development (cloning).¹¹⁶ Translated to human oocytes, this approach has been used to generate human ES cell lines.¹¹⁷

4. Altered nuclear transfer (ANT)

Classic SCNT approaches give rise to an early stage embryo capable of commencing embryonic development. Altered nuclear transfer methods aim at compromising this potential for embryonic development, e.g. by introducing genetic modifications into the donor nucleus, which eliminate the potential for placental development.¹¹⁸

5. Parthenogenetic ES cells

Using electric and chemical activation, oocytes can be induced to “commence” embryonic development without fertilization, a process referred to as *parthenogenesis*. A few studies have shown that this route can be used to generate blastocysts from human oocytes, which can serve as source for the derivation of parthenogenetic ES cells.¹¹⁹ The below Figure 1 provides an overview of these strategies in graphic form:

¹¹⁵ Gavrilov, S. et al. (2009), Non-viable human embryos as a source of viable cells for embryonic stem cell derivation, *Reprod. Biomed. Online* 18:301-8; Gavrilov, S. et al. (2011), Derivation of two new embryonic stem cell lines from non-viable human embryos, *Stem Cells International* 765378. doi: 10.4061/2011/765378; Zhang, X. et al. (2006), Derivation of human embryonic stem cells from developing and arrested embryos, *Stem Cells* 24:2669-76.

¹¹⁶ Wilmut, I. et al. (1997), Viable offspring derived from fetal and adult mammalian cells, *Nature* 385: 810–3.

¹¹⁷ Tachibana, M. (2013), Human embryonic stem cells derived by somatic cell nuclear transfer, *Cell* 153:1-11

¹¹⁸ Meissner, A. and Jaenisch, R. (2006), Generation of nuclear transfer-derived pluripotent ES cells from cloned Cdx2-deficient blastocyst, *Nature* 439:212-5

¹¹⁹ Mai, Q. et al. (2007), Derivation of human embryonic stem cell lines from parthenogenetic blastocysts, *Cell Res.* 17:1008-19; Lin, G. et al (2007), A highly homozygous and parthenogenetic human embryonic stem cell line derived from a one-pronuclear oocyte following in vitro fertilization procedure, *Cell Res.* 17:999-1007; Revazova, E.S. et al. (2007), Patient specific stem cell lines derived from human parthenogenetic blastocysts, *Cloning Stem Cells* 9:432-49.

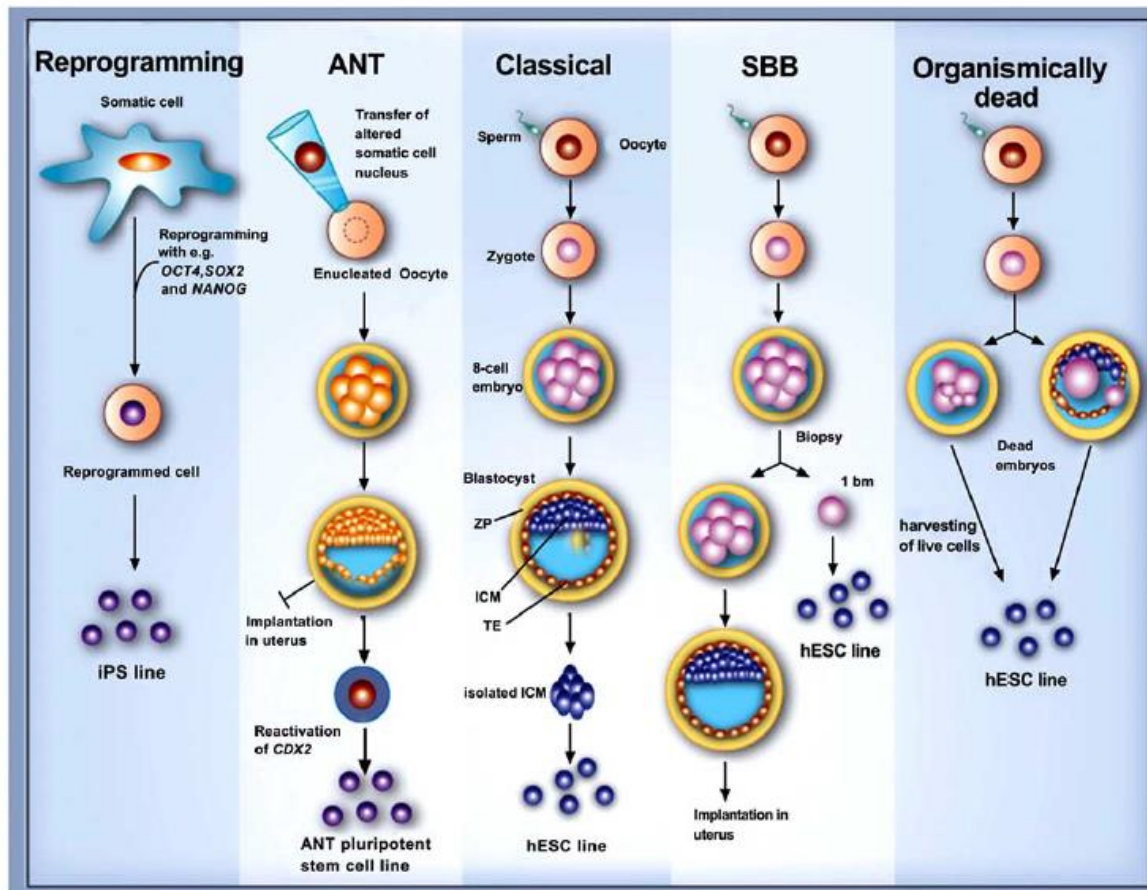


Figure 1: Classical and alternative strategies for the generation of hESC.¹²⁰

2. An overview of all the legal issues to be discussed for the subject

This report considers, whether subject matter is, or might be, excluded from patentability and what subject matter is or might be considered patentable in the field of stem cells and allied matter only. It should be noted that, in order to adhere to a factual consideration and presentation of the technology, a number of ethical, regulatory and medical issues were not discussed in detail or developed further in this written opinion.¹²¹

After an overview of the statutory sources (see below 3) and the current position of case law (see below 4) the following items are addressed in greater detail in light of both the technical developments as well as the developments in case law:

The patentability of inventions related to human cell lines such as adult stem cell lines, embryonic stem cell lines and induced pluripotent stem cell lines will be addressed (see below 5.1.);

The terms „human embryo“ (see below 5.2) and „industrial and commercial use“ (see below 5.3.) were evaluated in light of the current case law and the implications on the patentability of

¹²⁰ Source: Gavrilov et al. (2009), Alternative Strategies for the Derivation of Human Embryonic Stem Cell Lines and the Role of Dead Embryos, *Current Stem Cell Research & Therapy* 4, 81-86. - See Fig. 1 page 82. To the best of our knowledge implantation in the uterus has never been done in practice.

¹²¹ For a disagreement with the mandate of the group see dissenting opinion.

destructive/non-destructive methods of embryonic stem cell derivation and parthenogenesis were considered.

Finally implications of these developments shall be addressed (see below 5.4).

3. An overview of the statutory sources

3.1. Articles 5 and 6 of the Biotechnology Directive 98/44/EC

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Article 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
 - (a) processes for cloning human beings;
 - (b) processes for modifying the germ line genetic identity of human beings;
 - (c) uses of human embryos for industrial or commercial purposes;

For an overview of the corresponding recitals compare Annex 1.

3.2. Corresponding Articles/Rules EPC

Article 53(a) EPC

European patents shall not be granted in respect of:

- (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

...

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Rule 28 (a), (b), (c) EPC

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) uses of human embryos for industrial or commercial purposes;

Rule 29 EPC

(1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3.3. Overview on national legislation implementing Directive 98/44/EC

Several Member States of the European Union and contracting states of the EPC, in implementing Directive 98/44(EC) have passed national laws which further clarify and apply the norms set in Articles 5 and 6 of Directive 98/44. Member States acceding after the adoption of the Directive were automatically subject to the *acquis communautaire* and accordingly implemented the Directive.

The absolute majority of the EU Member States choose an identical wording for implementation of Art. 6 (2) c) without changes or additions: Belgium, Bulgaria, Croatia, Denmark, Finland, France, Greece, UK, Ireland, Latvia, Lithuania, Luxemburg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the Czech Republic, Hungary und Cyprus.

Five Member States have chosen a different implementation with regard to Art. 6 (2) c): Germany, Estonia, Italy, the Netherlands and Austria.

In the implementation laws of Austria, the Netherlands and Italy the qualification limiting the use of human embryos to a „use for industrial or commercial purposes“ is missing. These countries therefore exclude any use of human embryos *per se* from patentability.

In Estonia only the qualification of „uses of human embryos for commercial purposes“ was implemented.

Germany, Estonia and Austria have chosen a one-to-one implementation of Art. 6 (2) c) preserving the wording without changes or additions, but additionally refer to respective national fertilization

and embryo protection legislation for interpretation of this provision. For example, the **German Patent Act** expressly stipulates that in interpreting the Rules of the Patent Act, the corresponding provisions of the Embryo Protection Act have to be observed. This criminal Act regulates assisted procreation and prohibits *inter alia* the use of IVF techniques for purposes other than to initiate and pursue a pregnancy; artificial alteration of human germ line cells; cloning or a formation of human animal chimaeras and hybrids, and oocyte donation. However, since any national interpretation must fall within the scope of the Directive 99/44/EC this reference cannot lead to a deviating interpretation of the Directive.

Of all Member States, only Italy *expressly* exempts human embryonic stem cells and human embryonic stem cell lines from patentability. Italy excluded "the human body from the moment of conception" (...) in order to guarantee that patent law will be exercised with respect to the fundamental rights of the dignity and integrity of the human being and the environment" (Art 4 (1)a) and explicitly prohibited "any use of the human embryo, including human embryonic stem cell lines" (Art 4 (1)c(3)).¹²²

Of the EPC contracting states **Switzerland** (a) explicitly exempts from patentability "inventions the use of which violate human dignity", and lists among such explicitly a) procedures of cloning of human beings and the resulting clones; b) processes to produce chimeras from human germ cells, human totipotent cells or human embryonic stem cells and the beings produced thereof; c) processes of parthenogenesis by use of human germ cells and the produced parthenotes; d) processes for modifying the germ line genetic identity of human beings and the germ line cells thereof; e) unmodified human embryonic stem cells and stem cell lines; f) the use of human embryos for non-medical purposes." (Patent Act, 2 June 2007, Art. 2).¹²³

Fundamental rights perspectives and norms as set in Recitals 43 and 16, and referred to also in Article 16a, may become even more relevant in the future interpretation of the Directive. In national implementation acts of the Directive, e.g. France, Italy (and Switzerland) explicitly refer to human dignity, and Italy and Belgium to the European Court for Human Rights.

4. An overview of the current position taken by case law

Of particular significance are recent decisions of the CJEU that have been issued on the patentability of stem cell inventions both in the case C-34/10 *Brüstle v. Greenpeace* as well as in the decision in the case C-364/13 *International Stem Cells Cooperation v. Comptroller General of Patents*.

Regarding the position of the EPO, decisions of Boards of Appeal and the Enlarged Board of Appeal merit particular consideration.

¹²² Italy: Decreto-Legge 10 gennaio 2006, n. 3. Gazzetta Ufficiale – Serie Generale n. 8 del 11-1-2006. Conversione in legge, con modificazioni, N. 3760 – Gazzetta Ufficiale – Serie Generale n. 58 del 10-3-2006, testo in vigore dal: 12-1-2006.

¹²³ Switzerland: Bundesgesetz über die Erfindungspatente (Patentgesetz, PatG) Änderung vom 22. Juni 2007. All translations by Schneider, Original texts of national laws to be found in: Schneider (2010) "The European Patent System. Shifts in Governance through Parliaments and Civil Society" ("Das Europäische Patentsystem. Wandel von Governance durch Parlamente und Zivilgesellschaft"), p. 747-771, explanations on pp. 580-585.

4.1. Case C-34/10 Brüstle v. Greenpeace at CJEU and the corresponding decision of the German Federal Court of Justice

4.1.1. Case C-34/10

The case C-34/10 Brüstle v. Greenpeace arose in Germany from a patent of Prof. Oliver Brüstle covering neural progenitor cells, neuronal cells derived thereof and a method of their production from hESC (Human Embryonic Stem Cell) lines. The patent was originally filed in 1997 and granted by the German Patent Office in 1999. In 2004 Greenpeace filed a nullity action against the patent based on reasons of ordre public and morality. A decision of the German Federal Patent Court in 2006 rendered the patent partially invalid, eliminating all claims relating to cells derived from hESC lines. Following Brüstle's appeal against this decision, the German Federal Court of Justice (FCJ) referred the dispute to the CJEU, arguing that its decision in the case depends on the interpretation of Art. 6 of the European Biotech Directive asking the following questions:

“1. What is meant by the term 'human embryos' in Article 6(2)(c) of Directive 98/44/EC?

(a) Does it include all stages of the development of human life, beginning with the fertilisation of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied?

(b) Are the following organisms also included:

(1) unfertilised human ova into which a cell nucleus from a mature human cell has been transplanted;

(2) unfertilised human ova whose division and further development have been stimulated by parthenogenesis?

(c) Are stem cells obtained from human embryos at the blastocyst stage also included?

2. What is meant by the expression 'uses of human embryos for industrial or commercial purposes'? Does it include any commercial exploitation within the meaning of Article 6(1) of the Directive, especially use for the purposes of scientific research?

3. Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching,

(a) because the patent concerns a product whose production necessitates the prior destruction of human embryos,

(b) or because the patent concerns a process for which such a product is needed as base material?”

The CJEU held that

“1. Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions must be interpreted as meaning that:

– any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a ‘human embryo’;

– it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a ‘human embryo’ within the meaning of Article 6(2)(c) of Directive 98/44.

2. The exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6(2)(c) of Directive 98/44/EC also covers the use of human embryos for purposes of scientific research, only use for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it being patentable.

3. Article 6(2)(c) of Directive 98/44/EC excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.”

4.1.2. Decision of German Federal Court of Justice

Applying this ruling to the German case X ZR 58/07, the German FCJ in its final decision in the continued proceedings on November 27, 2012 changed the judgment of the Federal Patent Court and maintained the German patent 197 56 864 with the proviso that the embryonic stem cells must not be obtained by destruction of human embryos.

The patent was upheld as valid within the scope of auxiliary request 1, which adds in claim 1 the disclaimer “whereby no isolated purified precursor cells of human embryonic stem cells are used when embryos have been destroyed for their production” and in claims 12 and 16 adds the disclaimer “whereby no human embryonic stem cells are used when embryos have been destroyed for their production”.

4.2. Case C-364/13 International Stem Cell Corporation vs. Comptroller General of Patents, Designs and Trade Marks

International Stem Cell Corporation applied for two national patents for a technology that produces pluripotent stem cells from parthenogenetically-activated oocytes. The UK IPO rejected both applications on the grounds that the inventions in question entail uses and even the destruction of human embryos according to the CJEU’s answer to question 1 in C-34/10 and are therefore not patentable.

International Stem Cell Corporation appealed the decision of the Office to the UK courts claiming that as the activated oocyte, in the absence of paternal DNA, is not capable of becoming a human being. Accordingly the restrictions on patentability resulting from the Brüstle judgment should not apply to its technology.

The UK High Court of Justice, has asked the Court of Justice the following:

“Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings included in the term "human embryos" in Article 6(2)(c) of Directive 98/44/EC on the Legal Protection of Biotechnological Inventions?”

The court ruled as follows:

“Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions must be interpreted as meaning that an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a ‘human embryo’, within the meaning of that provision, if, in the light of current scientific knowledge, it does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to determine.”

4.3. Case law of the EPO

4.3.1. G 0002/06-WARF

So far, the most relevant decision regarding patentability of hESC-based inventions at the EPO has been the decision G 0002/06-WARF of November 25, 2008 issued by the EPO’s Enlarged Board of Appeal. It concerns the European patent application EP0770125 filed by the Wisconsin Alumni Research Foundation (WARF), which relates to “primate ES cells”.

In its decision T 1374/04, Technical Board of Appeal referred the following points of law to the Enlarged Board of Appeal:

- “1. Does Rule 23d(c) [now 28(c)] EPC apply to an application filed before the entry into force of the rule?
2. If the answer to question 1 is yes, does Rule 23d(c) [now 28(c)] EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which - as described in the application — at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?
3. If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?
4. In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: eg derivation from available human embryonic cell lines)?”

The Enlarged Board of Appeal held the following:

“Question 1: Rule 28(c) EPC (formerly Rule 23d(c) EPC) applies to all pending applications, including those filed before the entry into force of the rule.

Question 2: Rule 28(c) EPC (formerly Rule 23d(c) EPC) forbids the patenting of claims directed to products which - as described in the application — at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said, products are derived, even if the said method is not part of the claims

Question 3: No answer is required since Questions 1 and 2 have been answered with yes.

Question 4: In the context of the answer to question 2 it is not of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos.”

For the case law of the Technical Board of Appeal on human embryonic stem cells related inventions as well as the EPO’s position on IVF related inventions compare Annex 2 and Annex 3 respectively.

For the changed practice notices UK/IPO and the changed EPO Guidelines compare Annex 4.

5. An analysis of the various possible views

5.1. Patentability of human cells

In light of the Biotechnology Directive 98/44/EC and current case law cited above, the Group concluded the following with regard to patentability of human cell lines such as adult stem cell lines, embryonic stem cell lines and induced pluripotent stem cell lines (iPSC-lines).

There was unanimous consent in the group that isolated adult stem cells, as such, are not excluded from patentability pursuant to Article 53 EPC. No new issues with regard to adult stem cell line patentability could be identified.

With regard to the patentability of induced pluripotent stem cell lines, as such, the group could not identify questions, since they themselves are not capable of development into a human being and their derivation does not involve “uses of human” embryos by any definition of the term.

Totipotent cells are excluded from patentability (Article (5) of the Directive and Rule 29 (1) EPC)) (COM(2005)312 final)¹²⁴.

Equally excluded from patentability are processes for cloning human beings; and claims to the processes for modifying the germ line genetic identity of human beings (Article 6 (2) a) and b)).¹²⁵

With regard to embryonic stem cell patentability there are various issues that require understanding of the terms of the provisions of Art. 6 II lit. c) of the Biotechnology Directive. However, to put the

¹²⁴ See Chapter 2.2 in COM(2005) 321 final, : <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52005DC0312&from=EN>

¹²⁵ Although there have so far been very few applications claiming processes for modifying the germ line genetic identity this might gain relevance as the use of genome editing technologies in pluripotent and other stem cells and in early stages of human development, to correct genetic defects or introduce other potentially therapeutic changes, now provides vast scope for applications in human disease and health, including the potential for modification of the human germline, for an extensive discussion of many scientific, ethical and regulatory issues but not discussing questions of patentability see the Hixton Group „Statement on Genome Editing Technologies and Human Germline Genetic Modification“.

importance of this question into perspective it is noted that approximately 30 patents have been granted at the EPO so far which are dealing with hESC as explicit subject-matter.

5.1.2. Conclusion and recommendation

While claiming in its Recital 38 to provide clear guidance to the Member States in interpreting the reference to ordre public and morality in Article 6 (1), the Directive as such effectively did not provide sufficient clarification in regulating questions occurring with regard to the patentability of inventions related to human embryonic stem cells. Given that the Directive was issued before hESC were made publicly available, and as a consequence, contains no specific language relating to the patentability of hESC-based invention, varying interpretations have emerged in the Member States with regard to the interpretation of various terms in Article 6 (2) lit. c in particular “use for industrial and commercial purposes” and “human embryo”. Nevertheless none of the members of the subgroup endorses a redrafting of the Biotech Directive. Even though the provision of Art. 6 (2) lit. c of the Directive may not be perfectly clear, it has provided a sufficient framework for further legal development, and the case law has provided a relatively clear if not necessarily satisfactory interpretation of the provision (see below detailed conclusions in 5.2.3 and 5.3.3).

5.2. Meaning of the term “human embryo”

5.2.1. Relevant legal provisions

Relevant legal provision

Article 6 (2) (corresponding to Rule 28 (c) EPC)

On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(c) uses of human embryos for industrial or commercial purposes;

5.2.2. The term “human embryo”

Taking the definition of the European Court of Justice in his response to the first question in the judgment *Brüstle vs. Greenpeace* as a starting point, the court distinguishes three different entities that constitute a human embryo:

1. A human ovum after fertilisation,
2. A non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted (SCNT Somatic Cell Nuclear Transfer) and
3. A non-fertilised human ovum which division and further development have been stimulated by parthenogenesis

The Court held that the definition of the term “human embryo” must be uniformly understood throughout the territory of the Union in a wide sense, to assure necessary respect for human dignity.

Accordingly, any human egg cell must, as soon as fertilised, be regarded as a “human embryo”, since fertilisation commences the process of development of a human being.¹²⁶

Regarding the non-patentability of human embryonic stem-cell lines derived from a human fertilized ovum requiring its destruction in this process the group could not identify dispute if not based on a critique of the judgment as such. However, since the judgment is legally binding to all Member States, this shall not be discussed in further detail. Both the CJEU as well as national practice consider the fact that a destruction of a “human embryo” may have occurred at a stage long before the invention, which is what happens when stable established hESC lines are used as the starting material of the patented procedure, as irrelevant.¹²⁷ This is also in accordance with the standing practice of the EPO.

Non-patentability of cell lines obtained through somatic cell nuclear transfer is clear and undisputed.

In case C-364/13 the CJEU considered the definition of the term human embryo and delivered a complete reversal with regard to parthenotes, by deciding that human parthenotes are not “human embryos” because they do not in themselves have the inherent capacity of developing into a human being. Parthenotes are incapable of commencing the process of development into a human being. Therefore parthenotes are a source of human embryonic stem cells for use in patentable technologies provided such technologies fulfill all other criteria of patentability including ordre public and morality (Article 53(a) EPC/ Article 6 (1) of the Directive).

Accordingly the EPO has revised its practice following the ruling of C-364/13. In consequence, applying C-364/13, human embryonic stem cells (hES cells) derived from parthenotes do not require the destruction of a human embryo and are hence not excluded from patentability under Article 6(2)(c) of the Directive (Article 53(a) and Rule 28(c) EPC). However, this is first-instance and hence preliminary practice, which will be subject to review by the EPO’s boards of appeal.

On 5 June 2003 a protocol to derive human parthenogenetic embryonic stem (hpES) cells from activated oocytes (parthenotes) was disclosed in the PCT application WO 03/046141 (Advanced Cell Technology). From this date onwards, inventions relating to human pluripotent stem cells including hES cells, to their uses and to products derived from them are patentable (subject to fulfilling all patentability criteria) on the basis that these may be produced and put into practice using a method which does not involve destroying a human embryo.

Further clarifying its reasoning for this position in paragraph 39 of the decision, the CJEU states:

[The Biotech Directive] must be interpreted as meaning that an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a ‘human embryo’ [...], if [...] it does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to determine.

¹²⁶ Para. 24 et seq. and para 32 et seq., *Brüstle v. Greenpeace*, Case C-34/10, 18 October 2011.

¹²⁷ Para. 47 et seq. *Brüstle v. Greenpeace*, Case C-34/10, 18 October 2011.

In light of both the CJEU's decisions and definitions as well as the related reasoning, any of the three above mentioned entities constitute a human embryo provided that they are "inherently" "capable of developing into a human being".

The court thereby clarified that - for cells falling under the embryo definition - the entity has to have this capacity of developing into a human being intrinsically. The addition of a subsequent factor X that would have to be given or a procedure Y that would have to be subsequently applied is not sufficient. The vast majority of the Experts welcomed this concretization, since an interpretation including this broad understanding of such a definition ("able to commence the development of a human being"), i.e. also including the possibility that an addition of X or an application of Y is needed, would ultimately lead to an exclusion of patentability of any procedure that uses any random human cell, given that such a cell might actually be reprogrammed to a respective potency state (by SCNT, tetraploid complementation, or other means).

Other new methods, like the artificial creation of human germ cells may also become available that could lead to artificial creation of human embryo like entities. Inventions related to such methods or their products would be excluded from patentability. If these entities fulfill the definition used by the European Court of Justice of being "inherently" "capable of developing into of a human being", they would have to be considered "human embryos". New methods which could potentially lead to the creation of artificial germ cells or germ cell lines are excluded as such from patentability according to Article 5 and Recital 16 of the directive. Additionally, inventions involving an embryo produced by means of artificial germ cells should be treated in the same way as any inventions related to a 'natural' embryo produced by the fusion of an oocyte and a sperm cell.¹²⁸.

5.2.3. Conclusion and recommendation

Should the term "human embryo" be further clarified?

There are three categories of recommendations the Experts could make, here indicated with the option and the number of Experts who support it:

- 1) Taking no action (13 of 15)
- 2) Request a clarifying statement by the Commission (2)
- 3) Recommend legislation to make clear what is unclear (2 as a fall-back position to option 2).

A large majority (all but two Experts) of the Expert Group recommend that no action is taken to address the term "human embryo" even though a definition is missing in the Directive, which has led to legal uncertainty and differences between the Member States. However, ambiguity has been removed to a sufficient degree by subsequent CJEU decisions. What is to be understood as a "human embryo" was clarified by the first case C-34/10 *Brüstle v. Greenpeace* as an organism "capable of commencing the process of development of a human being". In C-364/13 *International Stem Cell Cooperation Corporation vs. Comptroller General* further clarification was achieved regarding the notion of an embryo by specifying that the first definition has to be understood as meaning that this organism needs to "in itself, have the inherent capacity of developing into a human being".

¹²⁸ For references and further explanations see dissenting opinion.

Two Experts request a clarifying statement by the Commission (or as a fall-back position legislation) to the effect that processes and products for creating synthetic gametes and synthetic embryos fall under the exclusions from patentability.

5.3. Meaning of the term 'use'

5.3.1. Relevant legal provisions

Relevant legal provision

Article 6 (2) (corresponding to Rule 28 (c) EPC)

On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

- (c) uses of human embryos for industrial or commercial purposes;

5.3.2. The term “use”

5.3.2.1 Meaning of the term “use”

Based on this preliminary definition, the Sub-Group discussed the meaning of term "use" in the light of the *Brüstle v. Greenpeace* decision of the CJEU and its implications.

The Directive declares unpatentable “uses of human embryos for industrial or commercial purposes”. What is meant by “use of a human embryo”? There are three possible meanings:

- (a) A process or substance which itself requires the use of a human embryo. For this to be the subject of a patent it would be necessary that the patent claim – the subject-matter protected by the patent – would itself specify as an element or part of an element a human embryo. Putting it another way to perform the patented invention you would have to use human embryos. We call this meaning the “strict” meaning because it clearly requires direct use of human embryos.
- (b) A process or substance which depends on a prior, “upstream,” destruction of a human embryo. We call this meaning the “middle meaning”: it takes into account the notion that any destruction of a human embryo may be considered contrary to human dignity and so an invention whose genesis involves such destruction it “tainted” by the earlier use.
- (c) A process or substance which depends on a prior, “upstream” non-destructive use of a human embryo. We call this the “widest meaning”.

No-one questions that the exclusion includes meaning (a). It is also clear from C-34/10 that the exclusion includes meaning (b) – the wide approach to “human dignity” adopted by the Court compels this conclusion, not having remained without criticism as having gone too wide,¹²⁹ a criticism that was also uttered by a number of Experts, as it departs quite considerably from well

¹²⁹ See Bonadio, E. (2012), *Stem Cell Industry and Beyond: What is the Aftermath of Brüstle*, *European Journal of Risk Regulation*, 93; Blance, S., *Brüstle v Greenpeace (C-34/10): The End For Patents Relating to Human Embryonic Stem Cells in Europe?*, *IP Europe Quarterly*; Harmon and Laurie, *Dignity, plurality and patentability: the unfinished story of Brüstle v Greenpeace*; and Burke, *Interpretive clarification of the concept of “human embryo” in the context of the Biotechnology Directive and the implications for patentability*.

known principles of patent law, such as that the invention is defined by the wording of the claims, and the deviation of such foundation principles could have wide ranging consequences if applied more widely. In particular patent law so far has never taken “upstream” uses into account as also stated by the CJEU in C-377/98, Kingdom of the Netherlands vs. European Parliament and Council of the European Union on the validity of the directive wherein the court phrases, that the directive concerns only “the grant of patents and whose scope does not therefore extend to activities before and after that grant, whether they involve research or the use of the patented products”.¹³⁰

The *Brüstle v. Greenpeace* case was concerned with an invention *inter alia* consisting of particular cells made from hESCs. So the “upstream” use was direct. What was not decided (because the Court was not concerned with the point) is the position where an invention is made using general scientific knowledge gained or gained in part by work involving destruction of hESCs. In one sense the invention required the destruction of an hESC or hESCs: but for the earlier work involving that destruction, the invention could not have been made. However the “but for” test is seldom a sufficient. So it may be that the *Brüstle v. Greenpeace* decision is limited to exclusion from patentability of inventions, which directly resulted from the destruction of an Embryo.¹³¹

It is also clear, that the use for human embryos for industrial commercial purposes as stated in Article 6 (2) (c) of the Directive also covers the use of human embryos for purposes of scientific research. Only use for therapeutic or diagnostic purposes, which are applied to the human embryo and are useful to it, is patentable.¹³² What is much less certain is whether the exclusion includes meaning (c) - the widest meaning. For it is by no means clear that non-destructive use of a human embryo is to be regarded as contrary to human dignity.

The CJEU in its answer to question 3 states that Article 6 II c) of the Directive “includes any invention of patentability wherein the technical teaching which is the subject matter of the patent application requires the prior destruction of human embryos or their use as a base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.”. This wording of the answer to question three equally allows for both of the reading alternatives.

The term “or their use as base material” could be interpreted as excluding *any* use of a human embryo from patentability, unless the invention is “for therapeutic and diagnostic purposes which are applied to the human embryo and are useful to it” (Recital 42). However, while this interpretation was put forward by two Experts, this is not the interpretation shared by the large majority of the group.

Such a reading of the CJEU judgement and the broad exclusion of *any* use of human embryos for third party interests could be backed by the legislative history Article 6(2)(c). Article 6(2)(c) was introduced as amendment 55 by the European Parliament, and held unpatentable “methods in which human embryos are used”. After acceptance by the Commission, this wording was changed in the Common Position adopted by the Council to “uses of human embryos for industrial and

¹³⁰ Para 79.

¹³¹ Two members wish to distance themselves from this paragraph, as they do not share this conclusion. See dissenting opinion.

¹³² Answer to question 2 of the *Brüstle v. Greenpeace* case.

commercial purposes".¹³³ However this could also be understood as introducing an additional limiting criterion and therefore narrowing the scope of the provision to not all uses but only such uses for industrial and commercial purposes.

To support the reading of the term use to mean "any use" the ratio legis of the exclusion of the use of human embryos from patentability is the protection of human dignity as a fundamental norm (see CJEU C-377/98), was evoked two Experts,¹³⁴ arguing that this would speak for a broad interpretation of "use". Accordingly the objective of Article 6(2)(c) in the light of this could be understood as the absolute protection of extra-corporeal human embryos from instrumentalisation as an object, and from exploitation serving foreign purposes.¹³⁵

Finally, supporting the widest interpretation of use as meaning "any use" two Experts argued that even if the CJEU Brüstle v. Greenpeace decision were completely silent about the patentability of methods and technologies which do not involve the destruction of human embryos, it would be a logical fallacy to deduce that this would then allow patentability of non-destructive uses of human embryos. The Court was not asked to judge on this question.

The same two Experts also argued that the list of inventions in Art 6(2) of Directive 98/44/EC was non-exhaustive and therefore did not cover all possible uses intended by the legislator. Several Recitals (e.g. 38 and 40) already provide further examples.

However, it is important to note that the vast majority of the Experts concluded, that when considering the context of this ruling in particular reason 47 of the judgment, it becomes evident that use as a base material is only excluded insofar as it relates to the destruction. Reason 47 reads:

"An invention is unpatentable even though its purpose is not the use of human embryos, where it concerns a product which production requires the prior destruction of human embryo or a process for which requires a base material obtained by destruction of human embryos".

Also all following reasons of the third question only deal with questions of the destruction of the embryo (reason 48, 49 and 50). This reinforces that the term 'use' should only exclude from patentability any invention that would implicate a destructive use of human embryos.

Furthermore, a statement of the court to going beyond destruction or destructive use as a base material would be ultra vires, since this did not form part of the question posed by the German Federal Court.

Finally, G 2/06 points out in Reasons, 21 ff, that before human embryonic stem cultures can be used, they have to be made. Since the only teaching in the referred case was the use (involving their destruction) of human embryos, the invention fell under the prohibition of Rule 28(c) EPC, [equivalent to Article 6 Directive]. Making a claimed product was the ordinary way commercially to exploit a claimed invention and fell within the monopoly granted. It is important to note that even

¹³³ For references, see Comments of the President of the EPO on G2/06, 2006, p. 38-39)

¹³⁴ This argument is also based on the „Edinburgh“ decision. See dissenting opinion.

¹³⁵ For references, see for instance Comments of the President of the EPO on G2/06, 2006, p. 41.

this broad reading of the term use including “upstream use” does not include “any upstream use” but only “destructive upstream use”. i.e. represents the “middle meaning” as discussed above.

Therefore, the majority of the Experts hold that the judgment should be understood to refer to “destructive use only”. If the interpretation would cover “any use” of embryos all inventions related to human embryo derived cell lines, were excluded from patentability.

Accordingly if only destructive use shall be excluded by the Article 6 II c) according to the Brüstle v. Greenpeace judgment, single blastomere biopsy technology is a candidate for possible non-destructive methods. In particular as reported inter alia by Chung et al. 2008¹³⁶ a derivation of hESC lines is possible without embryo destruction. It discloses an improved method for deriving hES cell lines from a single blastomere removed from an 8-cell human embryo. Single blastomeres were removed from the embryos by using a technique similar to preimplantation genetic diagnosis (PGD). The biopsied embryos were grown to the blastocyst stage and frozen. The biopsy procedure did not appear to interfere with subsequent normal blastocyst development of the parent embryo. The success rate of this new procedure is claimed to be similar to that of conventional hESC derivation techniques using blastocysts. The new improved method does not require co-culture with pre-existing hES cells, so destruction of a human embryo does not have to take place at this or any preceding stage.¹³⁷

Furthermore a reading, which would exempt “any use” of a human embryo from patentability, would not be consistent with **national practice**:

E.g. the German Federal Court in allowing auxiliary request 1, only excluded patent protection, if an embryo is destroyed during derivation of the cell line, by allowing a disclaimer that reads "wherein no human embryonic stem cells are used during the generation of which embryos have been destroyed".

This is also the position taken by the UK IPO in its changed practice notice after Brüstle v. Greenpeace, since it clearly refers only to destructive use of human embryos:

“The CJEU ruled that use of human embryos within the meaning of Article 6(2)(c) of the Directive occurs if the implementation of the invention requires the destruction of human embryos, even if the claims of the patent do not refer to the use of human embryos. The CJEU also ruled that the destruction may occur at any stage, including long before the implementation of the invention. Thus, the Office practice will now recognize that where the implementation of an invention requires the use of cells that originate from a process which requires the destruction of a human embryo, the invention is not patentable according to paragraph 3(d) of Schedule A2. For example, where the implementation of the invention requires the use of a human embryonic stem cell line the establishment of which originally required the destruction of a human embryo, the invention is not patentable.”¹³⁸

¹³⁶ Chung, Y. et al. (2008), Human Embryonic Stem Cells Lines Generated without Embryo Destruction. Cell Stem Cell 2:113-117.

¹³⁷ Two members of the Expert Group doubt the scientific validity of this publication. See dissenting opinion.

¹³⁸ Practice notice of 17 May 2012 <http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20120517.htm> replacing practice notice of 3 April 2009 <http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20090203.htm>

According to practice following decision G2/06 of the EBoA and judgment C-34/10 of the CJEU, the EPO also acknowledged patentability for inventions relating to stem cells that originated from a process, which does not require the destruction of human embryos. The following practice had been adopted:

a) a direct use of a human embryo wherein the embryo is destroyed is excluded from patentability under Article 53(a) and Rule 28(c) EPC. The patenting prohibition extends to cells derived directly and exclusively from such a destructive use (G2/06).

b) products derived indirectly from such destructive use are also excluded from patentability following G2/06 and CJEU C-34/10. The point in time of the embryo destruction is irrelevant.

c) a direct use of a human embryo wherein the embryo is not destroyed is also excluded from patentability under Article 53(a) and Rule 28(c) EPC. Rule 28(c) EPC excludes from patentability any use of human embryos and not only destructive uses. The patenting prohibition extends to cells derived directly from such a non-destructive use.

d) however, products derivable indirectly from a non-destructive use of a human embryo are in principle patentable under Article 53(a) EPC. Examples of such products of a non-destructive use of a human embryo are the human ES cell lines obtained through the single blastomere biopsy methodology disclosed by Chung on 10 January 2008.¹³⁹

Accordingly a number of European applications have been granted or proposed for grant, e.g. granted patent EP 2424977 (see also a related patent EP 2424976, claiming a method for obtaining the cells of the sister patent), granted patent EP 2139989 and granted patent EP 08839475 claiming human stem cells *per se* which has recently been proposed for grant as well as EP 2283117, which does not claim cells *per se*, but rather a method for purifying pancreatic endoderm cells from cells derived from pluripotent stem cells and was granted in October 2013 and mentioned in epi information 2/201. In this case a communication from the EPO dated 24.9.2012 makes explicit reference to the Chung publication.

The granted patents relate to stem cells produced by a non-destructive use of human embryos. The actual method for deriving the stem cells from human embryos, even in a non-destructive manner, is, however, not patentable. It was explained that co-cultivation of human blastomeres with hESCs would not be patentable.

However, according to the latest revision of its practice applying the ruling of C-364/13 as discussed above in chapter 5.2.2. the EPO now considers inventions relating to human pluripotent stem cells including hES cells, to their uses and to products derived from them as patentable from 5 June 2003 on. The above discussion is thereby rendered obsolete from the perspective of the understanding of the term “use” since these inventions may be produced and put into practice using a method which does not involve a human embryo already significantly before the above relevant date of 10 January 2008.

5.3.2.2 Claim scope vs. a whole technical teaching approach

¹³⁹ Chung, Y. et al. (2008), Human Embryonic Stem Cells Lines Generated without Embryo Destruction. *Cell Stem Cell* 2:113-117. See dissenting opinion.

A point of general importance is the question of claim scope vs. a whole technical teaching approach i.e. whether the formulation of the claims or the whole technical teaching is considered to be the relevant basis.

The *Brüstle v. Greenpeace* Decision confirmed an interpretation of Article 6(2)(c) of the Directive which excludes from patentability, an invention where “ *the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos....*”. In so deciding, the Court has established a critical but ambiguous test for determining the scope of the relevant exclusion and one, which deviates from established legal principles for providing transparency as to the valid legal scope of a patent. The meaning of the phrase “*requires the prior destruction*” is ambiguous as to the nexus between the claimed subject matter and any prior destruction of embryos: i) does this only apply in a direct lineage from the claimed subject matter or can inevitable but peripheral destruction required by the statistical reality of implementing this technology also bring claims within the excluded scope ? ii) if embryos which might otherwise be destroyed are maintained in a viable state even until patent expiry does this avoid the exclusion?

It is fundamental to the patent system that the claims define the scope of exclusivity and that the claims can be meaningfully analysed by third parties to assess the validity of the patent. If the claims protect subject matter which is non-novel, obvious or excluded from patentability on other grounds, then the patent will be invalid. The above comments in *Brüstle v. Greenpeace* mean that claims which fulfil all substantive grounds of patentability including not claiming excluded subject matter may still be invalid on the basis of an activity clearly not protected by the patent.

5.3.3. Conclusion and recommendation

Should the term “use” of a human embryo be further clarified?

There are three categories of recommendations the Experts could make, here indicated with the option and the number of Experts who support it:

- 1) Taking no action (13 of 15)
- 2) Request a clarifying statement by the Commission (2)
- 3) Recommend legislation to make clear what is unclear (2 as a fall-back position to option 2).

The Expert Group would welcome a clear indication in the guidelines of the EPO with regard to patentable subject matter regarding the patentability of a claim directed to a product that could be obtained by a method that did not involve the destruction of human embryos. It notes that the increasing body of EPO case law in this area will provide enhanced legal certainty. A large majority (all but two) of the Expert Group recommends that no action is taken to address the term “use”. Again, even though some ambiguity with regard to the understanding of the term “use” remains, the provision of Art. 6(2)© of the Directive has been further developed by case law and has provided a relatively clear interpretation.

Ambiguity remains with regard to the term “use” in the phrase “uses of human embryos for industrial and commercial purposes”. In particular, the statement of the CJEU in the *Brüstle vs. Greenpeace* decision that the “prior destruction of human embryos or their use as a base material”

is to be excluded from patentable subject matter remains to be understood. While most uncertainty regarding the understanding of the term “use” has been resolved by the two CJEU judgments, the remaining uncertainty regarding the third understanding of the term as including a prior, “upstream” non-destructive use of a human embryo can and should be resolved by an interpretation of the current case law as not including this overly broad interpretation of the term use.

The majority of the Experts (all but two) understand the judgment to refer to “destructive use only” and consider this the preferable interpretation. If the interpretation of “use as a base material” would cover “any use” of embryos, then all inventions related to human embryo derived cell lines or to other uses of embryos would be excluded from patentability, unless the invention is for “therapeutic and diagnostic purposes which are applied to the human embryo and are useful to it”. This would according to the majority of the Experts unduly extend the exclusion.

Even this interpretation of the provision was not considered satisfactory by a majority of the group. In particular the development of the case law, deviating from the claim wording to define the scope of the patent as well as including “upstream uses” in the exemption of Article 6(2)(c) led to severe criticism by the majority Expert Group.

A minority view taken by two Experts is that a clarifying statement of the Commission shall be requested (or as a fallback position legislation shall be recommended), to the effect that “any use of a human embryo is excluded from patentability, unless the invention is for therapeutic and diagnostic purposes which are applied to the human embryo and useful to it (Recital 42). This means that also products and processes based directly or indirectly on the method described by Chung et al. 2008 are unpatentable.

Finally, the views of what is contrary to *ordre public* have varied over time and will most likely vary in the future as well. Thus the court at a later point might reconsider the current position in time.

As stated at the outset of this report, many of our discussions that related to scientific and legal issues also had relevant ethical implications. However, our mandate did not include the analysis of ethics, which fall in the responsibilities of the European Group on Ethics in Science and New Technologies.

Enclosures to the subreport B:

Annex B1. Recitals of Directive 98/44/EC

Considering the aim of the Directive as stated in Recitals 13, 14, 16, 17, 18, 20, 21, 37 recalls that (i) the European Community's legal framework intend to lay down principles regarding the patentability of biological material; (ii) that patent legislation shall not replace national, European or international laws as to impose restrictions, controls or prohibitions for topics such as preservation of genetic diversity and compliance with certain ethical standards; (iii) restating that the human body, at any stage in its formation or development, including germ cells cannot be patented; (iv) that EU Member States shall provide incentives for encouraging research aimed, for example, at obtaining and isolated biological material from human body to be valuable to a medicinal product and ; and (v) that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element but to the exception if its commercial exploitation offends against ordre public or morality.

Regarding its relation to other European and international bodies of law, Recital 36 reiterates the importance of TRIPS while Recital 43 states emphasizes pursuant to Article F(2) of the Treaty on European Union the importance of the respect of the fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law

Recitals 37-42 refer to Art.6 directly and read as follows:

“(37) Whereas the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against ordre public or morality must also be stressed in this Directive;

(38) Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to ordre public and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability;

(39) Whereas ordre public and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention;

(40) Whereas there is a consensus within the Community that interventions in the human germ line and the cloning of human beings offends against ordre public and morality; whereas it is therefore important to exclude unequivocally from patentability processes for modifying the germ line genetic identity of human beings and processes for cloning human beings;

(41) Whereas a process for cloning human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being;

(42) Whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it;”.

Annex B2. Technical Board of Appeal case law

Further technical board of appeal case law of interest that relates to hESC is T1441/13, T1836/10, and T2221/10.

T2221/10 concerning the European patent application No. 03751238.1 held by Technion Research and Development Foundation, Ltd. is related to the patentability (Article 53(a) EPC in combination with Rule 28(c) EPC) of the following claim:

“1. A method of maintaining human embryonic stem cells in an undifferentiated state comprising co-culturing the human embryonic stem cells with a human foreskin feeder cell line, wherein cells of said human foreskin feeder cell line are growth suppressed by irradiation or treatment with an anti-mitotic agent and wherein said co-culturing is effected in the presence of serum or serum replacement, wherein said human foreskin feeder cell line is obtainable by:

(a) (...)

(b) culturing said foreskin cells in a culture medium including serum and/or serum replacement at a concentration range of 10% to 30%.”

Items 36 and 44 sum up the reasoning in the case to reject claim 1:

“36. In consequence, the claimed invention depends entirely on the use of HES cells, either obtained by de novo destruction of human embryos (cf. points 8 and 9, above) or by using established HES cell lines which initially were obtained by methods involving the destruction of human embryos (cf. points 10 to 29, above), both of which are excluded from patentability under the provisions of Article 53(a) EPC in combination with Rule 28(c) EPC.

Therefore appellant's sole request is not allowable. ...

44. The board observes that its decision in the present case, which is based on the decision G 2/06 of the Enlarged Board of Appeal, and which states that inventions which make use of HES cells obtained by de novo destruction of human embryos or of publicly available HES cell lines which were initially derived by a process resulting in the destruction of the human embryos are excluded from patentability under the provisions of Article 53(a) EPC in combination with Rule 28(c) EPC, is in line with decision C-34/10 of the ECJ.”

T1441/13 concerning the European patent application no. 02 799 217.1 held by Asterias Biotherapeutics Inc considered the patentability (Article 53(a) EPC in combination with Rule 28(c) EPC) of the following claim:

1. A method for obtaining polypeptide-secreting cells, comprising culturing pPS cells in activin A to differentiate the pPS cells to form gut endothelium, and culturing the gut endothelium in a mixture of islet cell differentiation factors (...) thereby obtaining a cell population in which at least 5% of the cells secrete at least one of the following proteins from an endogenous gene: insulin, glucagon, somatostatin, and pancreatic polypeptide.

The Board of Appeal stated in items 1-3 of the decision that this claim does not meet the requirements of Article 53(a) EPC based on the reasoning in G2/06 since at the relevant filing date of the application no method was available to achieve the invention without the destruction of human embryos.

The Board then had to consider the patentability (Article 123(2) EPC) of the following amended claim with a disclaimer (underlined):

"1. A method for obtaining polypeptide-secreting cells, comprising culturing pPS cells in activin A to differentiate the pPS cells to form gut endothelium, and culturing the gut endothelium in a mixture of islet cell differentiation factors (...), thereby obtaining a cell population in which at least 5% of the cells secrete at least one of the following proteins from an endogenous gene: insulin, glucagon, somatostatin, and pancreatic polypeptide wherein said pPS cells are not obtained by means of a process in which human embryos are destroyed.

The Board concluded in item 14 that the subject matter of the claim with this disclaimer was not disclosed in the application as originally filed since it was not possible to obtain the remaining subject matter that after this disclaimer was introduced into the claim. In other words the remaining subject matter was not sufficiently disclosed and could not be considered as part of the originally disclosed subject matter.

This decision is interesting because in its deliberation on the sufficiency of the originally filed application the Board stated in item 10.3 that:

"It is thus only the derivation method disclosed by Chung et al. in 2008, seven years after the priority date of the present application (7 December 2001), which for the first time has allowed the provision of hES cultures (cell lines) without destroying a human embryo in any production step."

T1836/10 on basis of the European patent application no. 05028411.6 held by W. Würfel related to the patentability (Article 123(2) EPC) of the following claim (translated):

1. Method for the isolation of pluripotent embryonic stem cells obtained from embryos in which

a) a channel is opened in the zona pellucida of a fixed blastocyst.

b) an instrument suitable for the mobilization of cells is led through the trophectoderm to the inner cell mass through this channel, and

c) the mobilized stem cells are suctioned off,

wherein carrying out steps a)-c) does not negatively influence the viability of the blastocyst, with the proviso that if the blastocyst is a human blastocyst, the cells that are obtained are not used in an industrial or commercial manner.

The Board did not examine patentability according to article 53 EPC. However with regards to a disclaimer trying to exclude potential future use of the stem cells in an industrial or commercial manner the Board stated that this is not part of the steps of the method of the claim because the claim is completed with the isolation of the stem cells and therefore concluded that this contravened Article 123(2).

Annex B3. IVF

While not being subject of the case law of Technical Boards it is noted that the EPO has a history of granting patents on IVF. With respect to the IVF methods, in the EPO's practice, the following are deemed unpatentable:

- claims to embryos as such (Rule 29 EPC = Article 5 of Directive 98/44/EC);
- claims to methods relating to the uses of embryos, unless they profit from Recital 42 (Rule 28 (c) = Article 6(c) Directive 98/44/EC);
- claims to germ cells as such ¹⁴⁰(Recital 16, Rule 29(1) = Article 5 Directive and the Guidelines G II, 5.3 under Reference of Recital 16 ¹⁴¹
- claims to methods relating to uses of embryos, if they are not for "therapeutic or diagnostic purposes" for which Art. 53 (c) has to be taken into account.

Case-by-case examination is called for when assessing inventions related to techniques and methods for improving the cultivation of pre-implantation embryos and the claims must be considered in light of description. The EPO will assess whether the invention referred to is or is not for the benefit of the embryo, e.g. to increase its chances for survival (according to Recital 42: "Whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it").

¹⁴⁰ EP 1263521 Ovasort, on maturation of human sperm cells (patent rejected in opposition procedure.)

¹⁴¹ The guidelines read: "In addition, the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions (see, however, G-II, 5.2). Such stages in the formation or development of the human body include germ cells (EU Dir. 98/44/EC, rec. 16)."

Annex B4. Practice notices UK/IPO, EPO

EPO

The EPO has revised its Guidelines for Examination in the EPO again following the ruling of C-364/13. The new version, valid from 1.11.2015 Part G Chapter 5.3. (iii) reads as follows:

“Uses of human embryos for industrial or commercial purposes

A claim directed to a product, which at the filing date of the application could be exclusively obtained by a method which necessarily involved the destruction of human embryos from which the said product is derived is excluded from patentability under Rule 28(c), even if said method is not part of the claim (see G 2/06, OJ 5/2009, 306). The point in time at which such destruction takes place is irrelevant (T 2221/10).

When examining subject-matter relating to human embryonic stem cells under Art. 53(a) and Rule 28(c), the following has to be taken into account:

- (a) the entire teaching of the application, not only the claim category and wording, and
- (b) the relevant disclosure in the description in order to establish whether products such as stem cell cultures are obtained exclusively by the use, involving the destruction, of a human embryo or not. For this purpose, the disclosure of the description has to be considered in view of the state of the art at the date of filing.

The exclusion of the uses of human embryos for industrial or commercial purposes does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it (EU Dir. 98/44/EC, rec. 42).

Judgments of the Court of Justice of the European Union on the interpretation of the EU Directive 98/44/EC are not binding for the EPO. Still, they may be considered as persuasive (T 2221/10 and T 1441/13).”

UK IPO

The changed practice notice after *Brüstle vs. Greenpeace* of the UK IPO reads as follows:

“The CJEU ruled that use of human embryos within the meaning of Article 6(2)(c) of the Directive occurs if the implementation of the invention requires the destruction of human embryos, even if the claims of the patent do not refer to the use of human embryos. The CJEU also ruled that the destruction may occur at any stage, including long before the implementation of the invention. Thus, the Office practice will now recognise that where the implementation of an invention requires the use of cells that originate from a process which requires the destruction of a human embryo, the invention is not patentable according to paragraph 3(d) of Schedule A2. For example, where the implementation of the invention

requires the use of a human embryonic stem cell line the establishment of which originally required the destruction of a human embryo, the invention is not patentable.”¹⁴²

¹⁴² Practice notice of 17 May 2012 <http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20120517.htm> replacing practice notice of 3 April 2009 <http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20090203.htm>

Annex B5. Dissenting Opinion on Stem Cell Report

Authored by Ingrid Schneider

The essence of this Opinion is supported by Christoph Then

This document is a dissenting opinion to the Report on patents in the field of human stem cells (hereinafter referred to as the "*Report*") of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering (E02973). As in the *Report*, this dissenting opinion is focused on human stem cells, human embryos and gametes as well as the application of the *ordre public* and morality clause of Art. 53 EPC and the respective Articles 5 and 6 in Directive 98/44/EC.

Summary

- The *Report* does not object to "non-destructive uses" of human embryos (cf. *Report*, page 18). Article 6(2)(c) of the Directive, however, considers unpatentable "uses of human embryos for industrial or commercial purposes" and does not distinguish between "destructive" and "non-destructive" uses of human embryos. It is arbitrary to exclude "destructive uses" from patentability and to allow "non-destructive" uses of human embryos.
- Even if "non-destructive" uses of human embryos were deemed patentable, the method disclosed in Chung et al. 2008 does not provide sound evidence for a "non-destructive" use of human embryos, contrary to the *Report* (page 20)
- Stem cells derived from activated human egg cells (parthenogenetic embryonic stem cells, hpES) are not identical to human embryonic stem cells, and therefore it is inadmissible to grant patents for processes and products on human embryonic stem cells, based on such hpES methods.
- Novel methods enable the use of iPS or embryonic stem cells to create artificial gametes and embryos genetically derived from two partners of same sex or from one individual only. It is recommended that both the Commission and the EPO specify and clarify that the term "germ cell" also includes artificially created egg and sperm cells, and that the term embryo also covers those artificially fused embryos.
- Genome editing technologies such as CRISPR have reignited the debate on human germline modification. It is paramount that both the Commission and the EPO specify and clarify that Articles 6(2)b and 6(2)c apply to CRISPR-Cas9 and CRISPR-Cpf1, if practiced in human germ cells and human embryos.
- Transparency and accountability of the work of the EPO requires disclosure of data on patent applications and grants, and revelation of changed granting practices in the EPO's Guidelines for Examination.

There is a strong need for a better balance in patent law to secure the proper interpretation of the *ordre public* and morality exemption in EU patent law, in accordance with the purposes and intentions of the EU legislator and with the EU's Charter of Fundamental Rights. This requires the Commission to take the initiative in strengthening the patent exclusions in Articles 5 and 6. In view of the rapid scientific developments it is urgently needed to provide an adequate clarification and

precise guidance for the correct interpretation of Directive 98/44/EC. This would comprise the following possibilities:

- new binding rules for the interpretation of current patent law without changing the text of Directive 98/44/EC;
- separate legislative action without altering the Directive as such;
- legislative action in order to incorporate robust and legally defined limits into Directive 98/44/EC.

Taking no political action is not and cannot be an option.

1. Introduction

Two members of the Expert Group could not consent to the Stem Cell *Report* and its opinion, even though these members share the majority's view that several ambiguities of the Biotech Directive with respect to human embryos have been sufficiently clarified by two CJEU decisions. However, in the members' opinion, the *Report* does not provide the basis for a balanced judgment, as several facts and perspectives have been downplayed or ignored. Lamentably, a number of important recent scientific developments in biotechnology, such as CRISPR genome editing as well as the creation of artificial gametes and embryos from stem cells, which have implications for patent law were also not taken up adequately, despite many attempts to address them within the Expert Group. The report is therefore unbalanced, as it did not appropriately represent diverging views on stem cell patentability and excluded further scientific developments which are relevant to the mission of the Expert Group and the provisions set in Article 16 of Directive 98/44/EC:

2. A teleological and historical interpretation of Directive 98/44/EC is needed

The Report correctly enumerates relevant legislative articles and case law. In its interpretation, however, the Report is to a large extent confined to the literal meaning of the statutory text. In contrast, this dissenting opinion considers it necessary to recall the legislative history to reveal the intent of the legislator and also to apply a teleological interpretation which takes the purpose of the law into account.

Therefore, this dissenting opinion departs from the view that in codifying Articles 5 and 6 of the Biotech Directive, the European legislator has created a genuine European *ordre public* which must be respected and should not be undermined by skilful drafting of patent claims or by twisting the law.¹⁴³ Inclusion of these Articles 5 and 6 were central preconditions for the European Parliament to pass Directive 98/44/EC in 1998, which it had rejected in 1995. These Articles and the respective Recitals preserve the democratic process of interpreting the *ordre public* clause in European patent law as a public policy clause.¹⁴⁴ Such an understanding, as expressed in the Biotech Directive, has

¹⁴³ See CJEU *Brüstle v Greenpeace*; EPO Enlarged Board of Appeal Decision G2/06 (WARF); and Comments of the President of the EPO on G2/06, 2006:

¹⁴⁴ The author's opinion is based on the insights into European Patent Governance gained in her academic work in which she has traced in detail more than two decades of the controversial legislative history of Directive 98/44/EC, from its first Agenda Setting in 1988 to its final adoption in 1998, and subsequent contentions on the implementation in all the members states in the EU and in the EPC. To this purpose,

incorporated two meanings and rationalities: First, the *ordre public* and public policy objections to patentability testify for a constitutionalisation of patent law, in which such clauses introduce constitutional standards for integrating patent law into the general European order of fundamental norms and values.¹⁴⁵ Second, the legal concept of "*ordre public* and morality" was interpreted by the European legislator with respect to consequentialist considerations: Patent law should be harnessed as one of several means to provide for innovation policies which are responsible, sustainable, and promote public welfare. The latter entails a modern understanding of patent governance as a mode of pro-active, socio-political regulation of technological trajectories, in accordance with European social values and norms as enshrined in the Charter of Fundamental Rights and in the precautionary principle.

Such a shift in the understanding of patent governance has resulted in special specifications and a non-exhaustive list of exclusions. For example, in exempting "(a) processes for cloning human beings; and (b) processes for modifying the germ line genetic identity" in Articles 6(2), the EU legislator has regulated scientific inventions which at that time were not yet feasible. The EU legislator thus provided patent legislation based on an anticipatory impact assessment, in which certain techniques were excluded from patentability because they were considered socially undesirable. Pursuing the idea of an ex-ante control of the social desirability of an invention, non-patent eligibility serves to express the societal disapproval of an invention. It is assumed that non-patentability induces a disincentive for respective research and development. It must be emphasised, however, that non-patentability is not penal prohibition. It only removes an incentive - the legal exclusivity of said invention and the expected return on investment - and thus it is used as an indirect mode of regulating R&D without forestalling the freedom of research.

Taken this understanding of Directive 98/44/EC into account, it would be inadequate to restrict the substance of these provisions by a too narrow or merely formalistic interpretation.¹⁴⁶ Implementing the law in both letter and spirit must become an integral part of granting practices at the European Patent Office, the national patent offices, of case law, and of interpretations issued by the Commission.

she has conducted thorough analyses of legal and policy documents and interviews with dozens of MEPs, legal scholars, and stakeholders. The analysis was successfully accepted as her habilitation thesis in political science in 2009 and was published as "The European Patent System. Shifts in Governance through Parliaments and Civil Society" in 2010 ("Das Europäische Patentsystem. Wandel von Governance durch Parlamente und Zivilgesellschaft", 771 pp., Frankfurt/New York: Campus). Parts of the analysis are available in English, e.g.: Schneider, I.: Can patent legislation make a difference? Bringing parliaments and civil society into patent governance, in: Haunss/ Shadlen (eds) *The Politics of Intellectual Property: Contestation over the Ownership, Use, and Control of Knowledge and Information*. Edward Elgar, 2009, pp. 129-157, and in: Schneider, I.: To Be or not IP? Exploring limits within patent law for the constitutionalization of intellectual property rights and the governance of synthetic biology in human health, in: *Law and the Human Genome Review*, No. 37, 2012, pp. 193-233.

¹⁴⁵ Geiger, Christophe 2006: "Constitutionalising" Intellectual Property Law? The Influence of Fundamental Rights on Intellectual Property in the European Union, in: *International Review of Intellectual Property and Competition Law* 37: 371-406; Kersten, Jens 2004: *Das Klonen von Menschen. Eine verfassungs-, europa- und völkerrechtliche Kritik*. Tübingen: Mohr Siebeck Torremans, Paul L.C. (ed.) 2015: *Intellectual Property Law and Human Rights*. Alphen: Kluwer Law International, 3rd revised edition

¹⁴⁶ "It must be borne in mind, further, that the meaning and scope of terms for which European Union law provides no definition must be determined by considering, inter alia, the context in which they occur and the purposes of the rules of which they form part." (CJEU, C-34/10, par. 31).

3. More empirical facts, statistics, and contexts must be taken into account

Another prerequisite for a report "on the development and implications of patent law in the field of biotechnology and genetic engineering" (Art. 16 (c), Directive 98/44/EC) would be to provide an account of the scientific evidence and empirical developments in science, law, economy and society in the field of stem cells.

Even though the *Report* gives in its Chapter 1 a short "overview of the relevant technology", it pays inadequate attention to the big shifts in the field of stem cell research which were caused by the advent of induced pluripotent stem cells (iPS cells) as another type of pluripotent stem cells that can be generated directly by reprogramming from mature adult cells. The iPS technology was pioneered in 2006 by Shinya Yamanaka in Japan and awarded the Nobel Prize in 2012. iPS has offered the means of producing patient-tailored cells without recourse to embryo destruction or cloning (SCNT). In contrast to human embryonic stem cells, iPS must not be derived from human embryos and can be used to create individual, patient-matched stem cell lines which in the future could be used to generate transplants without the risk of immune rejection. The field of adult stem cells has also developed further, and trans-differentiation of adult cells into other cells also allows for the preparation of patient-specific cells.¹⁴⁷ Thus, many technologies are available today which not only allow bypassing the need for human embryos, but also provide unlimited supplies of autologous cells. Therefore, the ethical controversies around human embryonic stem cells can largely be avoided by these new means. The advent of iPS cells has definitely changed the scientific field and mitigated the ethical debate because other sources of stem cells which do not rely on the use of human embryos have become available. Unfortunately, the *Report* concentrates on five "alternative" methods for deriving human ES cells which are hardly, if at all, used in experimental practices and - especially in comparison to iPS cells - are not in common use. This focus apparently has strategic and legal rather than scientific reasons.

The *Report* also fails to state that, by and large, the field of pluripotent stem cells is still in the stage of basic research, with very few clinical trials carried out to date. Moreover, as an expert hearing has confirmed, many hurdles and risks have to be overcome until therapeutic applications, both for iPS and embryonic stem cells, can become a clinical reality. Therefore, honest scientists have repeatedly warned against promising too much too early. Based on their characteristics of unlimited self-renewal and high proliferation rate, the risks associated with all pluripotent stem cell therapies include tumour formation, unwanted immune responses, and the transmission of infectious or other agents.¹⁴⁸

To date, several of the first broad patents on embryonic stem cells are soon to expire because they were filed 20 years ago. The European Patent Office has declined to provide statistics for the *Report*

¹⁴⁷ See for instance: Dave S 2014: Mesenchymal stem cells derived in vitro transdifferentiated insulin-producing cells: A new approach to treat type 1 diabetes. *Adv Biomed Res.* 2014 Dec 31;3:266; Forcales SV 2015: Potential of adipose-derived stem cells in muscular regenerative therapies. *Front Aging Neurosci.* 2015 Jul 13;7:123. doi: 10.3389/fnagi.2015.00123. eCollection 2015; Novak D, Weina K, Utikal J From skin to other cell types of the body. *J Dtsch Dermatol Ges.* 2014 Sep;12(9):789-92.

¹⁴⁸ This was the conclusion in the Expert Group's hearing with Prof. Peter Andrews on 16 September 2014, and it is also state of the art in scientific reviews. See Herberts, Carla A, Kwa, Marcel SG, Hermesen, Harm 2011: Risk factors in the development of stem cell therapy, *J. of Translational Medicine* 9, 29, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3070641/pdf/1479-5876-9-29.pdf>.

on the number of pending patent applications which involve human embryonic stem cells. Numbers, however, are important.

According to patent information based on the Global Patent Index, from 1986 to 2014 1476 patent applications involving human embryonic stem cells were filed as PCT applications, and 1019 European patent applications were filed at the EPO. According to the same source, by 2014 157 respective embryonic stem cell patents had been granted (See *Table 1* in Annex). *Table 2* (in Annex) lists respective embryonic stem cell patent applications per year from 1986 to 2014. It shows that up until 2008 fewer than 100 embryonic stem cell applications were published per year, with a steady increase up to the peak of 131 European patent applications in 2012 at the EPO. According to another statistics provided by the EPO in the course of the Expert Group's debates, and based on manual sorting of cases, applications reached a peak in 2011/2012 at about 105 PCT embryonic stem cell patent applications per year, and 100 respective European applications, and ranged between 20 and 100 EP embryonic stem cell patent applications per year between 2001 and 2013 (See *Table 3* in Annex).

Another counting method, based on manual examination of European patents granted on methods and products which include claims on human embryonic stem cells, has revealed 68 patents granted by the EPO from 1996 to 2015 (Information provided by Dr Ruth Tippe, 24.11.2015).

As the EPO's patent granting practice had been protracted due to legal uncertainties, a large number of patent applications involving human embryonic stem cells are still due to be granted. Therefore, the actual granting practice of the EPO matters.

Controversies concerning the EPO granting patents in the field of human embryonic stem cells started in 2000 at the occasion of the Edinburgh patent (EP 0695351), which sparked high media attention worldwide and for which the EPO admitted that it had granted the patent erroneously.¹⁴⁹ In the opposition proceeding, not only Greenpeace but also several EU Member States, namely Germany, Italy, and the Netherlands, were among the 14 opponents. Another important case law at the EPO was the WARF Case and its subsequent ruling G2/06 by the EPO's Enlarged Board of Appeal.

The first CJEU decision in Case C-34/10 *Brüstle v. Greenpeace* was fully in line with the former decisions of the EPO's judiciary and provided broad definitions for the term "human embryo", which hitherto had not been legally defined in EU law, and of the term "use for commercial and industrial purposes". The second CJEU decision in Case C-364/13 clarified "that an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a 'human embryo' (...) if, in the light of current scientific knowledge, it does not, in itself, have the inherent capacity of developing into a human being". Even though judgements by the CJEU on the interpretation of Directive 98/44/EG are not binding for the EPO, they are considered to be persuasive (T 2221/10 und T 441/13).

Despite these clear rules set in both the European Patent Organisation's and EU's jurisdictions, the EPO's granting practice has managed to grant patents around the prohibitions under Art. 53(a) and in Rule 28(c) (formerly Rule 23d c) EPC):

¹⁴⁹ See Schneider 2010 (Footnote 2), p. 403ff.

In 2013, the EPO took a single scientific publication by Chang et al. 2008 as justification to allow patents on products and processes "indirectly" derived from hESC, taking 10 January 2008 as a cut-off date. This practice was not revealed in the Guidelines for Examination, but was circulated in presentations of EPO examiners at patent law conferences and was later included in T1441/13.

In October 2015, the EPO in its granting practice preponed this cut-off date towards 5 June 2003 based on a protocol to derive human parthenogenetic embryonic stem (hpES) cells from activated oocytes (parthenotes) which was disclosed in the PCT application WO 03/046141. This international patent application was filed as European patent EP1456374. It contained only one claim, was only briefly examined, and was silently withdrawn on 25 November 2009 after fees were not paid several times.

Respectively, the EPO revised its Guidelines for Examination again (valid from 1 November 2015, Part G Chapter 5.3. (iii), see Annex 4 in the *Report*). Hence, the current EPO practice does allow for granting patents with claims involving human embryonic stem cells if such patent applications are filed after 5 June 2003 and other EPC conditions are met.

This dissenting opinion argues, contrary to the *Report*, that the current EPO practice does not comply with the provisions set in Directive 98/44/EC. To this purpose, it articulates a different interpretation of several legal provisions in the light of scientific developments, together with recommendations for clarification and specification by the Commission.

4. Article 6(2)(c) prohibits patentability of *all* third uses of human embryos

Article 6 (2) c of the Directive considered unpatentable "uses of human embryos for industrial or commercial purposes". The Directive does not distinguish between "destructive" and "non-destructive" uses of human embryos. Therefore, the Directive can only mean both possibilities of embryo use. If the legislator had intended to restrict the use to "non-destructive uses", it would have provided respective clarification in the Article and/or in the Recitals. It is arbitrary to exclude "destructive uses" and to allow "non-destructive" uses of human embryos.

Furthermore, the term "use" in patent law is normally understood in broad terms, for instance in the rules on second or further medical use of known pharmaceutical products.¹⁵⁰

Moreover, the CJEU in Case C-34/10 also states that Article 6 (2) c "includes any invention of patentability wherein the technical teaching which is the subject matter of the patent application requires the prior destruction of human embryos or their use as a base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos" (*Emphasis added*). The CJEU has not suggested that it wanted to allow non-destructive uses of human embryos, and there is no CJEU decision which has explicitly allowed it.

Therefore, the term "or their use as base material" must be interpreted as excluding *any* use of a human embryo from patentability, unless the invention is "for therapeutic and diagnostic purposes which are applied to the human embryo and are useful to it" (Recital 42).

¹⁵⁰ Second medical indication, EPO Guidelines for Examination; G. VI, 7.1.

In conclusion, only a broad interpretation of the term "uses" of human embryos in Article 6(2)(b) is in compliance with the Directive.

This interpretation has already been backed by the ruling of the EPO's opposition division in the "Edinburgh" case. Here, the board stated that "only a broad ruling of Rule 23d(c) can have been intended" by the European legislator:¹⁵¹

"If the legislator had intended a narrow interpretation of Rule 23d(c) (...) he would not have introduced both Rule 23d(c) and Rule 23e(1) into the EPC or correspondingly, Article 5(1) and Article 6(2)(c) in the Directive. Rule 23e(1) EPC excludes from patentability the human body, at the various stages of its formation and development, and recital 16 even states that the human body at any stage in its formation and development cannot be patented. The human embryo being an early stage in the development of the human body is thus already included in the scope of Rule 23e(1) EPC, and therefore, a narrow interpretation of Rule 23d(c) EPC would result in a 'redundancy' over Rule 23e(1) EPC. The fact that Rule 23d(c) EPC refers to 'uses' for 'industrial or commercial purposes' is not of relevance in the given context. (...) If the patenting of a product is ethically unacceptable, it is hardly conceivable that the patenting of 'uses' of this product can be judged differently. Thus it is considered that the exclusion of human embryos from patentability under Rule 23e(1) also pertains to the 'uses' of human embryos for whatever purpose."¹⁵²

As already stated as a minority opinion in the *Report*, the broad exclusion of *any* use of human embryos for third party interests is also backed by the legislative history of Article 6(2)(c) of Directive 98/44.¹⁵³ And even if the CJEU in Case C-34/10 *Brüstle v Greenpeace* had been completely silent about "prior destruction of human embryos", it would be a logical fallacy to deduce that this would then allow patentability of "non-destructive" uses of human embryos. The court was just not asked to judge this question.

In addition, it must be emphasised that the list of inventions in Art 6(2) of Directive 98/44/EC is non-exhaustive and therefore does not enumerate all possible uses intended by the legislator. Several Recitals (38 to 40) already provide further examples, for instance Recital 38 which states that "processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability".

The patent exclusion in Article 6 (2) c of Directive 98/44/EC is based on the Kantian rationale for human dignity, which states that humans must always be treated as an end in itself and not as a mere means to an end. Reference to human dignity as a fundamental norm for the interpretation of

¹⁵¹ The former Rule 23d (c) EPC is now Rule 28(c), the former Rule 23e(1) is now Rule 29(1) EPC.

¹⁵² Cited from the EPO, Edinburgh Case, Grounds for the decision, Application No. 94913174.2, 21.07.2003, p. 22.

¹⁵³ Article 6(2)(c) was introduced as amendment 55 by the European Parliament and held as unpatentable "methods in which human embryos are used". After acceptance by the Commission, this wording was changed in the Common Position adopted by the Council to "uses of human embryos for industrial and commercial purposes" For references, see Comments of the President of the EPO on G2/06, 2006, pp. 38-39).

the Directive is also made in Recital 16, reassured in CJEU Case C-377/98 *Netherlands v Parliament and Council* (par. 71 and 76), and reiterated by the CJEU in Case C-34/10 (par. 33-34).

In conclusion, considering the term "uses" of human embryos for industrial or commercial purposes" in Article 6(2)(b), only a broad and comprehensive interpretation of what constitutes "use" is in accordance both with the legal provisions and with the spirit, intentions, and will-formation of the European legislator. Reducing the term "uses" of human embryos to "non-destructive" uses only, as suggested in the *Report*, is not a justified means of interpretation.

5. Scientific validation: Chung 2008 does not provide sound evidence for "non-destructive" use of human embryos

In addition, several counter-arguments can be made with respect to some scientific arguments raised in the *Report*. The methods described in Figure 1 of the *Report* are misleading insofar as the figure might suggest that ANT (Altered Nuclear Transfer), SBB (Single Blastomere Biopsy), and "organismically dead" embryos would be on an equal footing with "classical" (hESC) or "reprogramming" (iPS) methods.

It can and should not be deduced from this figure that ANT and SBB are standard scientific practices which provide methods for producing pluripotent stem cells without the need to destroy the human embryo. ANT, SBB, and "arrested embryos" have been proposed and pursued by some researchers in order to overcome funding restrictions in the US and patent restrictions in Europe. However, those methods are highly controversial among researchers themselves, as they are fraught with scientific, logistical, medical, and ethical problems.¹⁵⁴ They have not been applied widely, and belong neither to standard practices in the lab nor have they ever, to our knowledge, been used in clinical practice.

In particular, it is inappropriate to use the method published by Chung et al. in 2008 as a loophole to allow patentability of methods and products "indirectly" derived from human embryonic stem cell lines for patents which were filed after 10 January 2008. Such a granting practice has been applied by the European Patent Office (EPO) and has been consented to by the majority of the members of the Commission's Expert Group in the *Report* (*Chapter* 5.3.2.1), arguing that such inventions could be based upon the derivation method disclosed by Chung et al. in 2008. Chungs' publication claims to have enabled the provision of hES lines without destroying a human embryo in any production step for the first time.¹⁵⁵ It is based on one single cell line (No. 5) said to be produced from a single blastomere, without co-culture with hESC.

However, the belief that Chung's method indeed changed the field of human embryonic stem cell research must be contested. The most relevant reasons for contestation are:

¹⁵⁴ Byrnes for instance states that ANT "as currently conceived, cannot realistically work": Byrnes WM 2007: The flawed scientific basis of the altered nuclear transfer-oocyte assisted reprogramming (ANT-OAR) proposal. *Stem Cell Rev.* 3(1): 60-65. For other objections see: Bobbert M 2006: Ethical questions concerning research on human embryos, embryonic stem cells and chimeras. *Biotechnol J.* 1(12):1352-69.

¹⁵⁵ Chung Y. et al.: Human Embryonic Stem Cells Lines Generated without Embryo Destruction. *Cell Stem Cell* 2008 2(2) 113-117, (published online 10 January 2008).

- 1) The existence of the cell line in question (No. 5 in Chung et al. 2008) is questionable, as it is not available to international researchers and no published studies are listed that utilise this cell line.
- 2) The method has no real world applicability with respect to the transfer of the remaining embryo (from which a single blastomere was extracted) to a woman's uterus. All biopsied embryos used by Chung et al. 2008 were frozen (cryopreserved) but never implanted.
- 3) The method applied in practice – taking a blastomere from a human embryo without destroying it – could cause harm to the embryo, without any indication and medical benefit for the embryo itself (hence, Recital 42 of Dir. 98/44 does not apply).
- 4) The blastomere taken from an embryo at the eight cell stage may still be considered totipotent.¹⁵⁶
- 5) On the basis of information currently available, to date no stem cell lines produced by this method are used in human embryonic stem cell research for therapeutic purposes.

In conclusion, the EPO appears to be using this method as a legal artefact without sufficient technical basis. One single cell line in a single publication does not provide sufficient and robust scientific evidence to legitimise such a far-reaching shift in patentability which has effects on several hundred pending human embryonic stem cell applications filed after 10 January 2008 (compare Table 1). Moreover, patents granted on the basis of this method would give adverse incentives to the field of stem cell research as it would encourage such methods fraught with medical and ethical problems. Alternative strategies which do not require human embryos at all, such as iPS cells, and further strategies which are based on "direct reprogramming" by "direct conversion" of human cells, and thus are "bypassing pluripotency", will be more conducive for stem cell research, especially as

¹⁵⁶ *Totipotent cells* are mentioned in the exclusions from patentability in Recital 38 of Directive 98/44/EC. In some national legislations, e.g. Germany, embryo is defined as any human totipotent cell which, exposed to the necessary conditions, has the potential to divide and develop into an individual (2002 Stem Cell Act, §3 (4)). There are different scientific definitions concepts of totipotency. It is agreed that blastomeres from the 2 to 4 cell stages are totipotent (See Geens et al. 2009: Human embryonic stem cell lines derived from single blastomeres of two 4-cell stage embryos, Human Reproduction, Vol. 24, No.11 pp. 2709–271.). According to scientific reviews of the state of the knowledge to date, totipotency can also not be excluded for blastomeres from the 6 or 8 cell stage because cleavage does not happen for all blastomeres simultaneously. For legal and ethical reasons, single blastomeres or manipulated human embryos are not transferred into a uterus to test their potency, and thus totipotency will never scientifically be proved in the human. (De Paepe C, Krivega M, Cauffman G, Geens M, Van de Velde H. 2014: Totipotency and lineage segregation in the human embryo. Mol Hum Reprod. 2014, Jul;20(7):599-618, p. 602). Therefore, two members of the Expert Group have drawn the conclusion that a single blastomere in the 8 cell stage, as used by Chung et al. 2008, has to be legally treated as totipotent. In their reasoning, as it is about human embryos, it is prudent to err on the side of caution. Such a position is also backed by the view of experimental animal studies in mice and rabbits, which have provided strong indications for totipotency of at least some of the blastomeres even in the 16 cell stage embryo (Ziomek et al. 1982, Chisholm/Fleming et al. 1984 and further references cited in: T. Littwin/ H. -W. Denker 2011: Segregation during cleavage in the mammalian embryo? Histochem Cell Biol (2011) 135:553–570).

recent research indicates that human pluripotent stem cells "*in vitro* can form structures that have some resemblance to embryos" post implantation.¹⁵⁷

In conclusion, it amounts to a violation of the will of the European legislator to bypass non-patentability of "uses of human embryos" (Art.6(2)c) by theoretical and technical means which are not based on sound, evidence-based science and real world applicability. Therefore, the Chung et al. 2008 technology is not an adequate means for allowing the granting of patents on inventions derived from human embryonic stem cells.

6. Parthenotes as stem cell source: not identical with embryonic stem cells

In the EPO's recent revision of the Guidelines for Examination, valid from 1 November 2015, and following the CJEU ruling in C-364/13, the EPO refers to the "state of the art at the date of filing" (see Annex 4 in the *Report*). As explained in the Report, "the EPO now considers inventions relating to human pluripotent stem cells *including hES cells, to their uses and to products derived from them as patentable* from 5 June 2003 on" (*Report* page 22, Emphasis added).¹⁵⁸ Accordingly, the EPO's new first-instance practice, adopted around October 2015, takes 5 June 2003 as new cut-off date, based on WO 03/046141 (*Report*, page 15).¹⁵⁹

Indeed, the PCT application WO 03/046141 (Advanced Cell Technology) discloses in Example 4 a protocol for the "Production of Autologous Cells by Parthenogenetic Activation of Oocytes" (pp. 45-46). However, the resulting cells are human parthenogenetic embryonic stem cells (hpES), which are deemed "ES-like cells" (p. 47). Therefore, even though these hpES cells are *similar* to human embryonic stem cells (hESC), they are *not identical* to hESC. Such a conclusion is scientifically inadmissible.¹⁶⁰

Activated human eggs called parthenotes do not involve the union of male and female germ cells, and so genetic material will be derived exclusively from the female oocyte donor.¹⁶¹ Therefore, they have important biological differences to fertilised human embryos.¹⁶² Even though "pESC are similar

¹⁵⁷ See: Pera Martin F et al. 2015: What if stem cells turn into embryos in a dish? in: *Nature methods*, vol. 12 (10) 2015: 917-919; also already Denker, Hans-Werner 2012: Time to Reconsider Stem Cell Induction Strategies. Review, in: *Cells* 2012, 1, 1293-1312.

¹⁵⁸ See end of Chapter 5.3.2.1, Chapter 5.2.2., and Annex 4 in the *Report*.

¹⁵⁹ This practice is, as always is the case, to be considered as preliminary and subject to review by the EPO's Boards of Appeal. As yet, it has not yet been confirmed by case law. The EPO Boards of Appeal's latest decision on this matter, T 1808/13, considered 2007 as the cut-off date for stem cells derived from parthenogenetic embryos (referring to Documents D23 and D21).

¹⁶⁰ Swelstad BB, Kerr CL 2009: Current protocols in the generation of pluripotent stem cells: theoretical, methodological and clinical considerations, in: *Stem Cells Cloning* 22(3):13-27.

¹⁶¹ Cibelli JB, Cunniff K, Vrana KE. 2006: Embryonic stem cells from parthenotes, in: *Methods Enzymol.* 418: 117-35; Kim K, Ng K, Rugg-Gunn P, et al. 2007: Recombination Signatures Distinguish Embryonic Stem Cells Derived by Parthenogenesis and Somatic Cell Nuclear Transfer. *Cell Stem Cell* 1:346-352.

¹⁶² Brevini TA/ Gandolfi F. 2008: Parthenotes as a source of embryonic stem cells, in: *Cell Proliferation* 41 Suppl 1: 20-30.

to ESCs", they lack paternal imprinted genes.¹⁶³ This is one of the reasons why parthenotes normally do not develop into full human beings.¹⁶⁴

Moreover, the conclusion drawn by the EPO from the CJEU judgment in C-364/13 is wrong. The CJEU was only asked whether parthenotes were included in the term "human embryos" in Article 6(2)(c) of Directive 98/44/EC. The CJEU responded that

"Article 6(2)(c) (...) must be interpreted as meaning that an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a 'human embryo', within the meaning of that provision, if, in the light of current scientific knowledge, it does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to determine."

Hence, the court neither took a decision as to whether parthenotes are eligible for patent nor whether processes to obtain parthenogenetic embryonic stem (hpES) derived from parthenotes are patentable. Parthenotes may fall under the exclusions in Art. 5 and Art. 6(1) of Directive 98/44/EC.

But even if these aforementioned products and processes were patentable, we consider the conclusion drawn by the EPO that human embryonic stem cells (hESC), their uses, and the products derived from them are patentable to be incorrect, because hpES are not identical to hESCs.

Moreover, we would like to draw attention to the fact that the literature has described cases which demonstrate the ability to produce the birth of live parthenogenetic mice which were able to produce offspring when the appropriate imprinting of key genes by a maternal genome were expressed.¹⁶⁵ In humans, this concept was also demonstrated in a single case report of spontaneous parthenogenetic chimerism in which the patient survived with a mixed makeup of normal and parthenogenetic cells.¹⁶⁶ Therefore, the question as to whether human parthenotes in itself have the inherent capacity of developing into a human being has not yet conclusively been answered in scientific knowledge.

¹⁶³ Daughtry B/ Mitalipov S. 2014: Concise review: parthenote stem cells for regenerative medicine: genetic, epigenetic, and developmental features, in: *Stem Cells Translational Medicine* 3(3): 290-298.

¹⁶⁴ Wu Q, Kumagai T, Kawahara M, Ogawa H, Hiura H, Obata Y, Takano R, Kono T. 2006: Regulated expression of two sets of paternally imprinted genes is necessary for mouse parthenogenetic development to term, in: *Reproduction*. 131(3): 481-488.

¹⁶⁵ Kono T/ Obata Y/ Wu Q et al. 2004: Birth of parthenogenetic mice that can develop to adulthood, in: *Nature*.;428 (6985): 860-864; Loebel, David A. F. / Tam, Patrick P. L. 2004: Genomic imprinting: Mice without a father, in: *Nature* 428, 809-811; Wu Q, Kumagai T, Kawahara M, et al. 2006: Regulated expression of two sets of paternally imprinted genes is necessary for mouse parthenogenetic development to term, in: *Reproduction* 131(3): 481-488.

¹⁶⁶ Strain L/ Warner JP/ Johnston T/ Bonthron DT. 1995: A human parthenogenetic chimaera, in: *Nature Genetics* 11(2): 164-169. Also cited in Swelstad BB, Kerr CL 2009: Current protocols in the generation of pluripotent stem cells: theoretical, methodological and clinical considerations, in: *Stem Cells Cloning* 22(3):13-27 on p. 20.

7. The creation of artificial gametes and embryos must remain exempted from patentability

In Chapter 5.2.2., the *Report* correctly states:

"Other new methods, like the artificial creation of human germ cells may also become available that could lead to artificial creation of human embryo-like entities. Inventions related to such methods or their products would be excluded from patentability. If these entities fulfil the definition used by the European Court of Justice of being "inherently" "capable of developing into of a human being", they would have to be considered "human embryos". New methods which could potentially lead to the creation of artificial germ cells or germ cell lines are excluded as such from patentability according to Article 5 and Recital 16 of the directive. Additionally, inventions involving an embryo produced by means of artificial germ cells should be treated in the same way as any inventions related to a 'natural' embryo produced by the fusion of an oocyte and a sperm cell."

However, the *Report* does not make sufficiently clear that the term "uses of human embryos" in Article 6(2)(c) may also extend to uses of human embryos in which an embryo is being technically created. It is important to take recent developments of such possible "constructive uses" of human embryos into account. The term "constructive use" comprises the creation of an artificial embryo by means other than normal in-vitro fertilisation (IVF). One example for such a new method for the construction of an embryo is "mitochondria replacement", also termed "three-parent babies".¹⁶⁷

Another novel method for the construction of an embryo by new means is to use iPS or embryonic stem cells to create artificial gametes and embryos. Using their own genetic material, the latter technology might allow same-sex-partners (e.g. two males) to create an embryo that is genetically related to both partners. It might also allow one individual to reproduce without another genetic parent by conjoining artificially created male and female germ cells from a single individual.¹⁶⁸

¹⁶⁷ In "mitochondria replacement", also termed "three-person in vitro fertilisation", an embryo with genetic material from three different people (two females and one male) is created, which also results in inheritable genetic modification (changes that would be passed on to future generations). Some observers have warned that this would open the door for human germline modification. (Darnovsky, Marcy 2013: A slippery slope to human germline modification. The United Kingdom's decision to trial the technique of mitochondrial replacement is premature and ill-conceived. *Nature* 499, 127, 11 July 2013).

¹⁶⁸ For the scientific background, see the report of the German Ethics Council: "Scientists have already been successful in developing germ line cells from iPS cells and cultivating them into fully functional germ cells following implantation in the gonads of animals. In animal experiments, sperm and egg cells artificially produced from such iPS cells have, through fertilization, lead to the creation of viable mice. It cannot be ruled out that, in future, this technology could be applied to human reproduction in constellations where procreation by natural means is impossible. Same-sex couples could, for example, produce children that are genetically related to both parents. The method could even be used to combine artificially created male and female germ cells generated from the same individual, resulting in an embryo. This raises an issue that is at least related to concerns regarding cloning: although the embryo is not a clone, it has only one genetic parent." (See for references: "Ethics Council sees need for clarification regarding artificially created germ cells and embryos" 15.09.2014, p.4, <http://www.ethikrat.org/files/recommendation-stem-cell-research.pdf>. It should be noted that a review article in 2000 already noted as a conclusion "Alternative sources of gametes are not merely science fiction, but already are a concrete fact." (Tsai et al. 2000: Alternative sources of gametes: reality or science fiction? *Human Reproduction* 15(5):988-98, p. 995).

In light of these recent developments, it is recommended that both the Commission and the EPO specify and clarify that the term “germ cell” (Directive 98/44/EC, Recital 16) applies not only to naturally created egg and sperm cells, but also includes artificially created egg and sperm cells (for example from iPS cells).

For the time being, the EPO's interpretation of patent exclusions related to germ cells appears to be as follows: The Guidelines for Examination in the EPO explicitly state in G-II, 5.3 that according to Rule 29(1) EPC, the human body, at the various stages of its formation and development, [...], cannot constitute patentable inventions. Such stages in the formation or development of the human body include germ cells (Directive 98/44/EC, Recital 16). It follows that human germ cells, be they artificially created or naturally occurring, are plainly unpatentable under the EPC. Germ cells are mentioned in Recitals 16 and 38¹⁶⁹, which have an impact on the interpretation of Articles 5 and 6. Germ cells, in particular oocytes, are relevant inter alia in the above mentioned use of parthenotes as a source of human embryonic stem cells and in SCNT techniques, where the resulting cloned embryo could be used for the derivation of human embryonic stem cells. SCNT, being a process for cloning human beings, is explicitly excluded from patentability under Rule 28(a) EPC. It is worth noting that, according to the Guidelines for Examination in the EPO, G-II, 5.3, for the purpose of this exception, a process for the cloning of human beings may be defined as any process, [...], designed to create a human being with the same nuclear genetic information as another [...] human being (EU Dir. 98/44/EC, rec. 41). However, that conjoining of artificially created male and female germ cells from a single individual is functionally equivalent to a (cloned) human embryo would require scientific and legal clarification.

In any event, such methods for producing artificial embryos and the resulting entity itself should not be eligible for patentability, either under either Article 6(2)(a)/ Rule 28(a) EPC (cloning), under Article 6(2)(b) /Rule 28(b) EPC (modification of the germ line genetic identity of human beings), under Article 5(1)/ Rule 29(1) EPC (the human body at the various stages of its formation and development), or ultimately under Article 6(1)/ Art. 53(a) EPC. It is necessary for both the Commission and the EPO to specify and clarify that such methods and products would fall under the prohibitions of Articles 5 and 6 of Directive 98/44/EC.

Here again, it is necessary to stress that such a provision of non-patent eligibility would not ban respective research, but would remove some commercial incentives for such research and development. As patents are granted according to the "winner-take-all" principle, only the first inventor who has filed the patent gets the temporary exclusivity. Hence, patents can have an accelerating effect on spurring such new techniques. Democracy, however, needs time to deliberate whether such new forms of procreation should be made available or not.

Proceeding with caution and without patents as an incentive for the construction of artificial gametes and embryos will allow European society sufficient time to debate whether such developments are socially desirable or not and whether national legislation of such developments

¹⁶⁹ Recital 38 refers to processes to produce chimeras from germ cells or totipotent cells of humans and animals, which are excluded from patentability under Art. 53(a) EPC. A narrow interpretation of this wording suggests that totipotent cells are only excluded when used for chimeras. A broad interpretation means that totipotent cells are excluded anyway. The author follows the second interpretation, as totipotent cells are equivalent to a human embryo, which is excluded in Article 5(1)/ Rule 29(1) EPC.

should be set on the agenda. Granting patents on such inventions for creating artificial gametes and embryos would set both an incentive for pursuing such research and an unfavourable precedence for other areas of law.

Moreover, it is important to state that any use of human egg cells for third parties and/or non-procreative purposes, for instance for parthenotes or for SCNT as sources of human embryonic stem cells, also carries the risk for women to be exploited as oocyte providers. The 2005 UN Declaration on Human Cloning (59/280) called upon the nations "to prohibit all forms of human cloning", both reproductive cloning and research cloning (SCNT). It also called upon Member States "to take measures to prevent the exploitation of women in the application of life sciences".¹⁷⁰ This call was reiterated in a resolution of the European Parliament.¹⁷¹

In conclusion, "constructive uses" of human embryos and gametes, by the creation of artificial gametes from stem cells, and by the conjoining of such artificial germ cells to a totipotent cell must remain exempted from patentability. Such techniques increase the risks of inducing and transmitting serious harms to the embryo and developing human being. Such techniques also presuppose that women provide a vast amount of oocytes for enucleation and/or act as surrogates to carry the artificially created embryo to term. Hence, they rely on the instrumentalisation of women and violate their dignity. For cross-compliance and cross-coherence of law, it is important that patent law adheres to higher ranking legal norms such as the wellbeing of the child-to-be and the dignity of women.

8. CRISPR must not be patentable for human germline modification

In Chapter 5.1., the *Report* correctly states: "Equally excluded from patentability are processes for cloning human beings; and claims to the processes for modifying the germ line genetic identity of human beings (Article 6 (2) a) and b))." In the corresponding footnote 17, it rightly refers to "recent genome editing technologies in pluripotent and other stem cells and in early stages of human development". However, the *Report* fails to elaborate on these new genome editing technologies and the scientific and legal debate associated with it, as one would expect in such a *Report* on the scientific developments and implications (Art. 16 (c) of Directive 98/44/EC).

It must be noted that recent scientific advances in genome editing have received high attention in science, policy, and the public. CRISPR-Cas9 and CRISPR-Cpf1 (Clustered Regularly Interspaced Short Palindromic Repeats) promise precise, fast, inexpensive, and easy to handle ways of genome editing and can be employed in all kinds of DNA. These and other genome editing techniques such as Zinc-finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs), and oligonucleotide directed mutagenesis (ODM)¹⁷² have been hailed as revolutionary with significant advantages for

¹⁷⁰ United Nations Declaration on Human Cloning (59/280). Resolution adopted by the General Assembly at its 82nd meeting, on 8 March 2005. <<http://www.un.org/law/cloning/>

¹⁷¹ European Parliament 2005: Planned egg cell trade. Resolution on the trade in human egg cells. P6_TA(2005)0074; <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2005-0074+0+DOC+XML+V0//EN>. See in particular Numbers 9-13.

¹⁷² Church, G., Regis, E. 2012: *Regenesi*s. How synthetic biology will reinvent nature and ourselves. Basis Books: New York; Gaj, Thomas et al. 2013: ZFN, TALEN, and CRISPR/Cas-based methods for genome engineering. Review, in: *Trends in Biotechnology*, 31(7): 397-405.

research and therapeutics as well as for economics and intellectual property¹⁷³ However, if genome editing techniques such as CRISPR were applied in heritable germline modification, they could have an unpredictable effect on future generations. Hopes and fears are not only present in media and policy debates, but also among researchers themselves. On the cautious pole of the spectre, scientists in Europe and the US have called for a moratorium and a public debate on CRISPR in the human germline.¹⁷⁴ On the other pole, researchers in China have conducted first experiments in using CRISPR for editing the genomes of nonviable human embryos.¹⁷⁵ UK funders have signalled support for germline-editing research,¹⁷⁶ and parts of the international scientific community, such as the Hinxton Group, have recommended that editing of the human genome in embryos should be allowed for basic research and suggested that the door should not be totally closed towards allowing genetic engineering of humans in the future.¹⁷⁷

Ledford, who mentions around 200 patent applications worldwide, recognises that “a patent battle” has intensified with a sharp increase in patent filings in 2014.¹⁷⁸ Kupecz refers to anonymous ‘third-party observations’ filed at the EPO aimed at preventing the granting of a European patent.¹⁷⁹ For Europe, our own tentative research has revealed more than 150 patent applications at the European Patent Office and 50 patents granted, of which were four granted to the US Broad Institute of MIT and Harvard and its member Feng Zhang. Some of the patents granted include the disclaimer “not for human germ line”.

The potential for using this technology in germ cells and embryos, or in stem cells which were later introduced in enucleated oocytes (SCNT), has definitely reignited the debate on human germline interventions. At present, however, human germline editing on human embryos in the clinical context is prohibited in more than 40 countries worldwide, including 14 European

¹⁷³ Ledford, Heidi 2015: CRISPR, the disruptor. A powerful gene-editing technology is the biggest game changer to hit biology since PCR. But with its huge potential come pressing concerns, in: *Nature* 522: 20-24.

¹⁷⁴ Baltimore, D. et al. 2015: A prudent path forward for genomic engineering and germline gene modification, *Science* 348: 36-38; Lanphier, Edward/ Urnov, Fyodor et al. 2015: Don't edit the human germ line, in: *Nature* 519(7544): 410 – 411; Leopoldina 2015: The opportunities and limits of genome editing. Leopoldina, acatech and Union of the German Academies of Science, Statement, September 2015, available at: http://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2015/stellungnahme_genome_editing_2015.pdf; BBAW (Berlin-Brandenburg Academy of Sciences and Humanities) 2015: Human genome surgery – towards a responsible evaluation of a new technology, available at: www.gentechnologiebericht.de/bilder/BBAW_Human-Genome-Surgery_PDF-A1b-1.pdf.

¹⁷⁵ Liang, Puding/ Yanwen, Xu et al. 2015: CRISPR/Cas9-mediated gene editing in human tripronuclear zygotes, in: *Protein and Cell* 6(5): 363–372; Cyranoski, David/ Reardon, Sara 2015: Chinese scientists genetically modify human embryos. Rumours of germline modification prove true — and look set to reignite an ethical debate, in: *Nature*, April 22, 2015.

¹⁷⁶ Joint statement of UK science bodies 2015: Genome editing in human cells – initial joint statement“, available at: <http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Genome-editing/WTP059704.htm>; Sample, Ian 2015: GM embryos: time to decide, say scientists, *The Guardian*, 2 September 2015, p.1-2.

¹⁷⁷ Hinxton Group 2015: Statement on Genome Editing Technologies and Human Germline genetic Modification, available at: http://www.hinxtongroup.org/hinxton2015_statement.pdf

¹⁷⁸ Ledford, Heidi 2015: CRISPR, the disruptor, in: *Nature* 522, June 04, 2015: 20-24.

¹⁷⁹ Kupecz, András 2014: Who owns CRISPR-Cas9 in Europe? in: *Nature Biotechnology* 32(12): 1194–1196.

states.¹⁸⁰ International and European regulations also consider human germline modification as unethical human experimentation or as abuse of human rights.¹⁸¹

Article 6(2)(b) of Directive 98/44/EC excludes patentability for "processes for modifying the germ line genetic identity of human beings". However, at the international level, there is no legal consensus as to whether human embryos are to be defined either as "human beings" or as "human life", with the latter implying less legal protection.

The European Court of Human Rights in *VO v. France*, and referring to the Oviedo Convention on Human Rights and Biomedicine, also observed that at European level,

"there is no consensus on the nature and status of the embryo and/or foetus. (...) At best, it may be regarded as common ground between States that the embryo/foetus belongs to the human race. The potentiality of that being and its capacity to become a person – enjoying protection under the civil law (...) require protection in the name of human dignity, without making it a "person" with the "right to life" for the purposes of Article 2."¹⁸²

Therefore, it is paramount that both the Commission and the EPO specify and clarify that Articles 6(2)b and 6(2)c, which exclude patentability of human germline modification and the use of human embryos for commercial and industrial purposes, apply to CRISPR-Cas9 and CRISPR-Cpf1 if practiced in human germ cells and human embryos. Only such clarifications will ensure that patents do not serve as incentives to pursue such controversial research which is contrary to European values, *ordre public*, and public policy.

9. Conclusions

More public debate, deliberations in the European Parliament and the Council, and inclusion of civil society organisations is needed in determining the appropriate interpretation of Directive 98/44/EC. At present, the discussion is often confined to patent attorneys, patent lawyers, and officials of patent offices, and thus often restricts reasoning to formalistic legal arguments. The Expert Group could have been an opportunity for a broad deliberation following Habermasian standards on discourse. Unfortunately, it has not used this opportunity, as arguments and validity claims brought forward in many instances were not refuted by reasoned argumentation but just cut off by the power of majority votes. Furthermore, the European Patent Office's granting practice and governance structures lack transparency and accountability to the citizens of Europe, an issue which needs to be addressed in current patent reforms. More transparency and an overhaul of its governance structure would be welcomed both by the national and European legislators and by the general public. It would also be in line with the EPO's public mission and with the principle of disclosure, which is one of the fundamentals of patents' legitimacy. Transparency and accountability

¹⁸⁰ Ishii, Tetsuya/ Araki, Motoko 2014: International regulatory landscape and integration of corrective genome editing into in vitro fertilization, in: *Reproductive Biology and Endocrinology* 12(108),

¹⁸¹ The UNESCO's Universal Declaration on the Human Genome and Human Rights indicates in Article 24 that "germline interventions" could be "contrary to human dignity." The Council of Europe's Convention on Human Rights and Biomedicine indicates in Article 13 that "an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants."

¹⁸² European Court of Human Rights, Case of *VO v. France*, Application no. 53924/00, 08.07.2004, Point 84. p. 38.)

of the EPO would first require providing data on the stem cell patent applications filed and granted, and second, for the EPO's granting practices on human embryonic stem cells, revealing the scientific and legal rationales of the EPO's new interpretation of the EPC's Article 53(a) and Rule 28 with reference to Chang et al. 2008 and PCT application WO 03/046141 in the EPO's Guidelines for Examination.

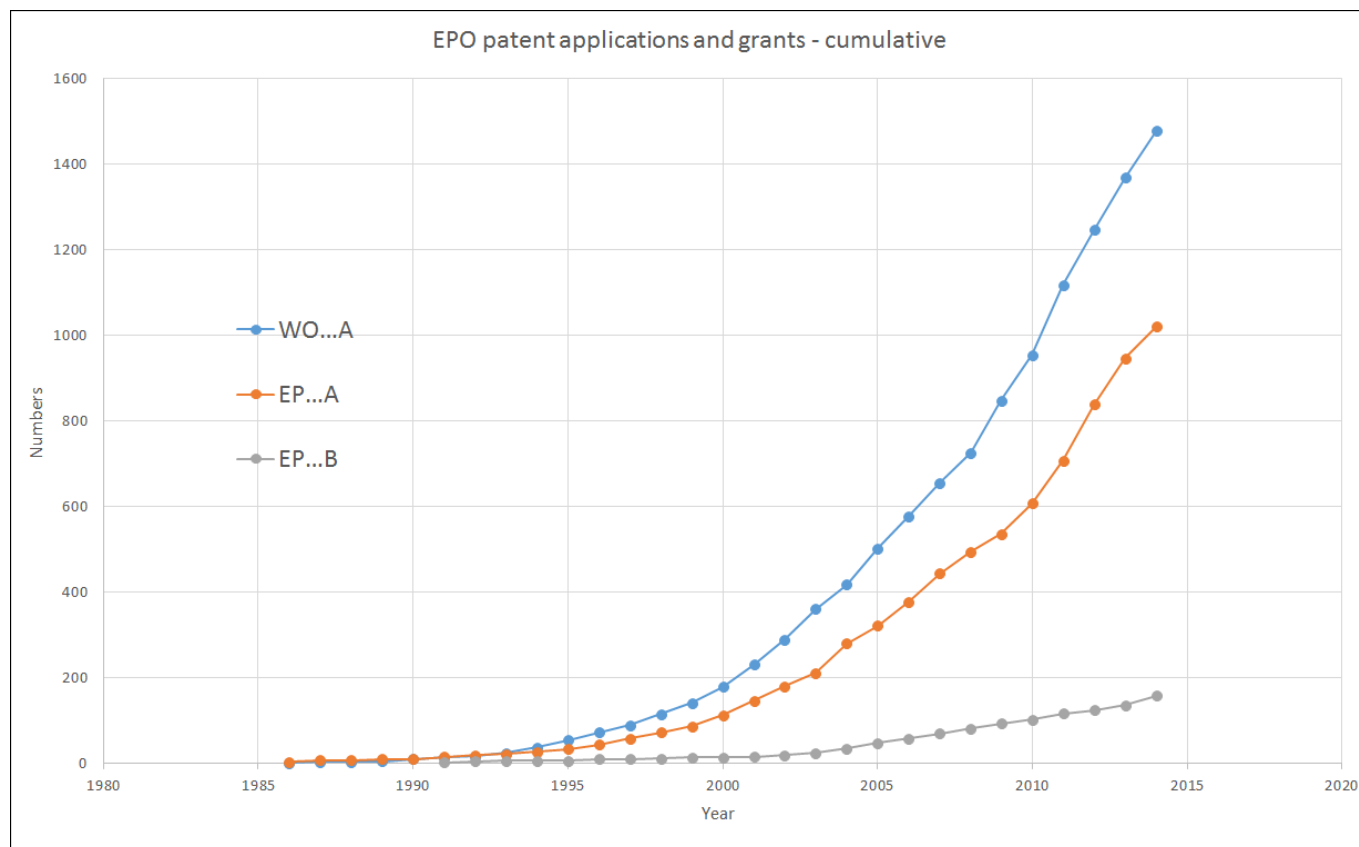
Moreover, the European patent system urgently needs to be democratised to serve the public interest and to comply with the social contract upon which it is constituted. A broader view on both the empirics and impact of patents is needed which recognises that patents are embedded in social and economic contexts; therefore, interpretation of legal statutes must not be confined to a literal interpretation, but must also include the history and the purpose of the EU Biotech Directive as well as the context of development and implications in its application.

There is a strong need for a better balance to secure the proper interpretation of the *ordre public* and morality exemption in European patent law in accordance with the purposes and intentions of the European legislator and with the EU's Charter of Fundamental Rights. This requires the Commission to take the initiative in strengthening the patent exclusions in Articles 5 and 6.

The first step to be taken by the Commission should be to provide adequate clarification and precise guidance for the correct interpretation of the EU Biotech Directive, as indicated in this dissenting opinion. These clarifications would establish new, binding rules for the interpretation of current patent law without changing the text of Directive 98/44/EC. As a fall-back position, a further step could be a separate legislative action without altering the Directive as such. Another step, and a last fall-back position in case the former provisions were unsuccessful, would be legislative action that may include a thorough revision of the EU Biotech Directive in order to incorporate robust and legally defined limits of patentability. Contrary to the views expressed in the majority opinion of the Expert Group, taking no political action is not and cannot be an option.

ANNEX

**Table 1: EPO Patent applications and grants on human embryonic stem cells
(1986-2014, cumulative)**



Source: Global Patent Index

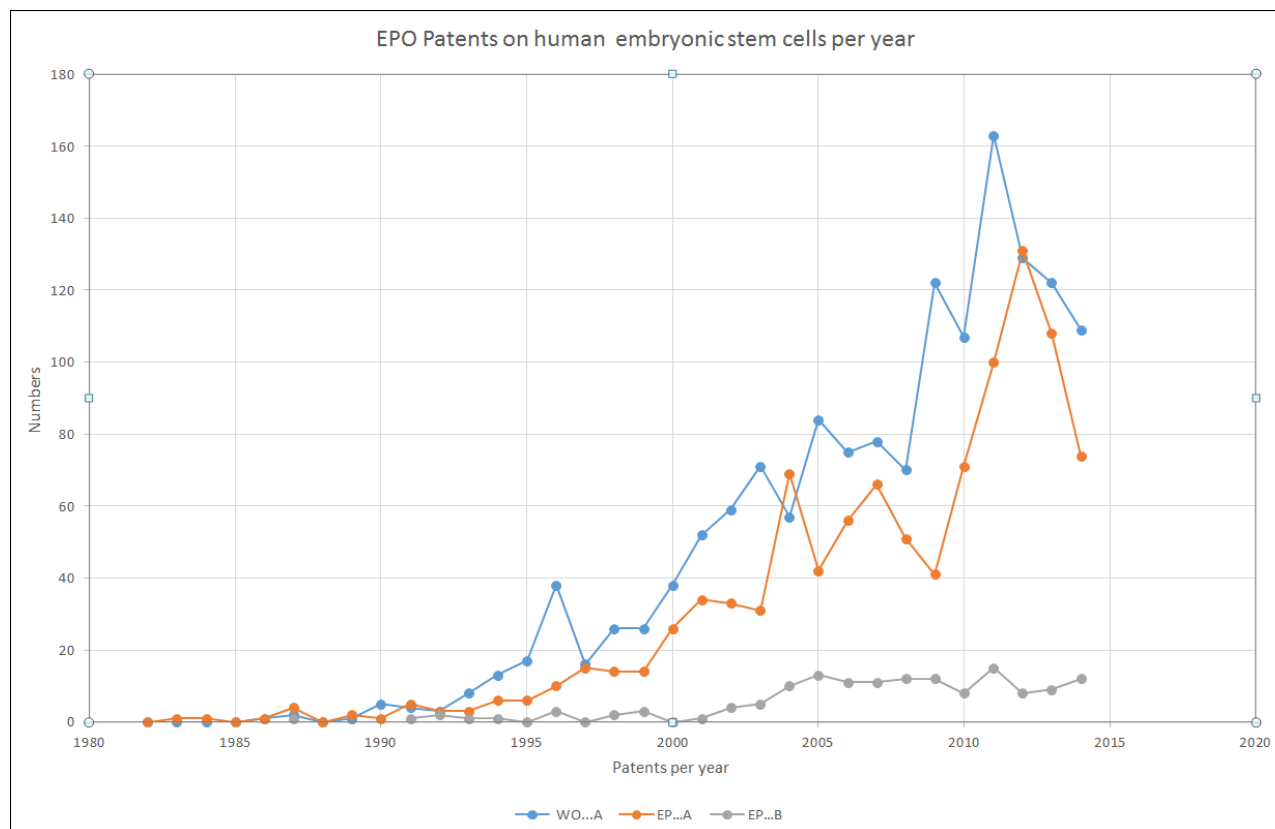
(Mainly based on classification IPC=C12N0005 and English title or abstract = embryonic or pluripotent or totipotent)

WO...A = PCT Applications

EP...A = European Applications

EP...B = Granted European Patents

Table 2: EPO Patent applications and grants on human embryonic stem cells (1986-2014, per year)



Source: Global Patent Index

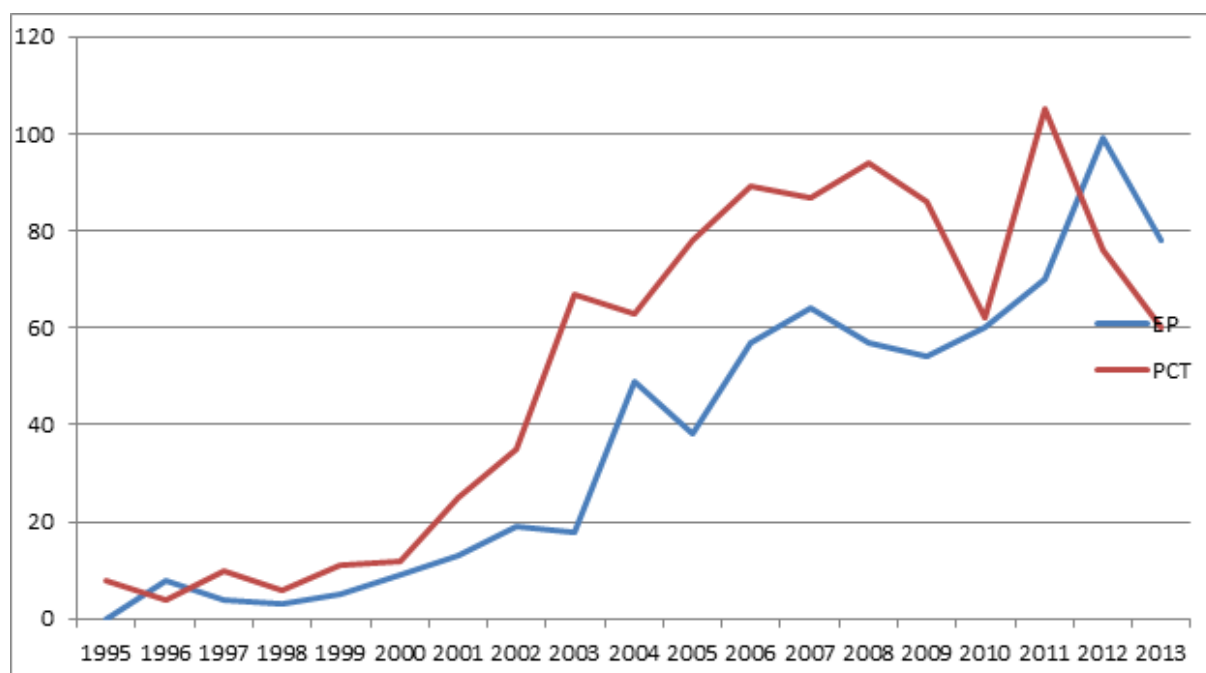
(Mainly based on classification IPC=C12N0005 and English title or abstract = embryonic or pluripotent or totipotent)

WO...A = PCT Applications

EP...A = European Applications

EP...B = Granted European Patents

Table 3: Number of published embryonic stem cell patent applications per year (1995-2013), as provided by source EPO



Source: European Patent Office, based on manual sorting of cases.

This statistics had formed part of the draft report of the Expert Group but was removed because the majority considered that the value of any statistics is limited, as they are all inexact.

C. Subreport on the Scope of Protection of Patent Claims Directed to Nucleic Acid-Related Inventions

1 Introduction

In December 2013, the European Commission organized an expert group pursuant to Article 16(c) of the Biotechnology Directive 98/44/EC to provide a report on the development and implications of patent law in the field of biotechnology and genetic engineering.

This report generally relates to the breadth of the scope of protection afforded by a patent claim to a nucleic acid molecule and in particular to the concept of “absolute product protection” for a nucleic acid molecule, where a patentee is awarded protection for a nucleic acid molecule per se, regardless of the manner in which the nucleic acid molecule was obtained and irrespective of the any intended use of the nucleic acid molecule.

The report first summarizes the historical development of absolute product protection in Europe, then provides relevant passages of the Biotechnology Directive 98/44/EC and the transposition of the Directive into National Law and into the European Patent Convention, and finally, examines recent developments in European patent law stemming from the Court of Justice of the European Union (CJEU) in decision C-428/08 relating to the scope of protection conferred by a patent claim directed to DNA, and in particular to isolated genomic DNA, i.e. the genetic material of living beings, as well as the implications of these developments.

A detailed discussion on the possible interpretations and resulting implications of the Biotech Directive in so far as it relates to absolute product protection of nucleic acids can be found in a previous Commission Report¹⁸³, which was published prior to CJEU decision C-428/08.

The report considers the opinions of the majority and minority of the Experts. One expert has provided a dissenting opinion which is attached herewith.

2 Historical Aspects of Patent Protection for Chemicals/Pharmaceuticals

In an article entitled “Patent Laws in Regard to the Protection of Chemical Industry that was published in 1921 in Transactions of the Kansas Academy of Science, Vol. 30, pp. 39-44, the author L. E. Sayre makes reference to the work of Dr. F. E. Stewart of Philadelphia that was published in the Proceedings of the American Pharmaceutical Association, February, 1917, and provides the following citation:

Medicines are excluded from patent protection in Germany, France, Austria-Hungary, Italy, Japan, Denmark, Norway, Sweden, Portugal, Russia and a number of other countries. Other classes of inventions excluded from patent protection in many countries, as well as in Germany, are foods, chemical products, and inventions relating to war material. In all of these countries

¹⁸³ “Patenting DNA Sequences (polynucleotides) and Scope of Protection in the European Union: an Evaluation,” S. Bostyn, 2004 (ISBN 92-894-7674-5).

exclusion from protection of inventions relating to medicines or foods does not generally extend to those relating to processes or apparatus for their manufacture.

The relevant German Law dated from 1877 and was amended in Germany in 1967 to allow for the protection of chemical/pharmaceutical products. Absolute product protection for isolated naturally occurring products was subsequently established in a series of decisions of the German Federal Supreme Court¹⁸⁴.

The relevant French law dated from 1844 legislation and was amended in France in 1978 to remove the ban on protection on pharmaceuticals per se.

In the United Kingdom, section 38A of the Patents Act read in 1919:

In the case of inventions relating to substances prepared or produced by chemical processes or intended of food or medicine, the specification shall not include claims for the substance itself except when prepared or produced by the methods or processes of manufacture particularly described and ascertained or by their obvious chemical equivalents.

Hence, while protection for chemical substances, medicines and food could be obtained in the form of a “product-by-process” claim, absolute product protection was not possible. However, this restriction was removed by the Patents Act of 1949. Absolute product protection for these subject matters has been available in the United Kingdom since that time.

In Italy, pharmaceutical patents were banned until 1978 when the EPC came into force.

The earliest version of the European Patent Convention, which entered into force in late 1977, also contained Article 167(a) which temporarily reserved the right for the Contracting State to provide that:

European patents, in so far as they confer protection on chemical, pharmaceutical or food products, as such, shall, in accordance with the provisions applicable to national patents, be ineffective or revocable; this reservation shall not affect protection conferred by the patent in so far as it involves a process of manufacture or use of a chemical product or a process of manufacture of a pharmaceutical or food product.

This reservation was utilized, for example, by Austria until October 1987 and partially by Spain (chemicals/pharmaceuticals) and Greece (pharmaceuticals) until October 1992.

Since then, it is generally believed that the protection conferred by a claim in a nationalized European patent in the various Contracting States and the protection conferred by a National patent within the European Union on a chemical as such or pharmaceutical as such is absolute, i.e. the protection is not limited by the method by which the chemical/pharmaceutical is produced and equally protects all uses of the patented product. This was also expressed in point 5 of the decision G2/88 of the Enlarged Board of Appeal of the European Patent Office in 1989:

It is generally accepted as a principle underlying the EPC that a patent which claims a physical entity per se, confers absolute protection upon such physical entity; that is,

¹⁸⁴ “Antamanid” GRUR 1978, 238; “Menthonthiole” GRUR 1978, 702; “Imidazoline” GRUR 1972, 541 (543)

wherever it exists and whatever its context (and therefore for all uses of such physical entity, whether known or unknown).

One exception to this is the protection attributed to a pharmaceutical or diagnostic agent by a so-called “second medical indication” or “Swiss-type” claim or the related “purpose-limited” product claim. Claims of this format contain a novel use of a previously known pharmaceutical/diagnostic agent. But this exception in fact creates an exception to the novelty requirement that anything known in the state of the art can no longer be protected by a patent, more than being an exception to the concept of absolute product protection. Hence, while such claims are limited to the pharmaceutical use recited in the claim, this “restriction” is in fact an extension of protection which permits the inventor to establish novelty, and therefore patentability, for a medical/diagnostic indication of a substance although that substance was already known in the art.

Based on the above, modern European patent law evolved over the last 100 years from various, different national legislations which provided or denied patent protection for chemical and/or pharmaceutical products as such to a harmonised position that grants absolute product protection for chemical and/or pharmaceutical products as such and even extends this protection to novel medical and diagnostic uses of known substances in the form of purpose-directed product protection.

3 Historical Aspects of Patent Protection for Nucleic Acids

Historically, the patentability of individual nucleic acids or compounds comprising nucleic acids did not pose any particular challenge to the existing rules governing the patentability of chemical substances in general.

Since its founding, the European Patent Office has continued to grant thousands of patents containing claims encompassing nucleic acid molecules such as genomic DNA with a known function, and the Contracting States of the European Patent Convention have continued to validate these patents. While most of these patents were granted after the Directive was transposed into national law and integrated into the European Patent Convention, many were granted and subsequently upheld by the Board of Appeal of the EPO prior to the Directive. For example, EP 91 539 was filed in 1983 and was upheld by the Board of Appeal of the European Patent Office in decision T128/92, which was well before the Directive. It contained a claim 1 directed to “A DNA fragment comprising a DNA sequence coding for a polypeptide having human interleukin-2 activity, said polypeptide being selected from the following group...”. This patent and similar cases granted and considered under appeal at the EPO before the Directive¹⁸⁵ did not seem to raise much public discussion and were not opposed by non-commercial entities.

However, recent developments in molecular biology over the past 25 years or so have led to the ability to decipher the genetic elements of living organisms, which consist of nucleic acids, on a large scale. While strictly speaking, the individual genes and the entire genome of humans and other living organisms and viruses are essentially composed of the chemical substances deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), the fact that these nucleic acids encode the hereditary

¹⁸⁵ For example T656/94 and T923/92

information of humans (and all animals and plants) has ignited a controversial discussion whether the nucleic acid sequences or partial sequences of genes should be considered patentable, and if so, to what extent (see Recital 22 of the Directive).

The first patent that gathered broader attention by non-commercial entities was the patent on human relaxin, EP 112 149, which was granted in 1991, was opposed in 1992 and was upheld in decision T272/95 decided by the Board of Appeal after the EU Directive came into place in 2002 and after the EPO had voluntarily adopted certain aspects of the Directive into the Implementing Regulations of the European Patent Convention.

In T 272/95, the Board of Appeal of the European Patent Office issued a decision affirming the patentability of human (and animal) genes. This decision related to a patent that described the nucleic acid sequence encoding the human hormone relaxin, which was derived from material isolated from the uterus of a pregnant female patient. The main claim of the patent was directed to:

1. A DNA fragment encoding human H2-preprorelaxin, said H2-preprorelaxin having the amino-acid sequence set out in Figure 2.

Granted claims 2 to 7 and 11 (partly) related to further DNA fragments encoding H2-relaxin. Claims 8 and 9 were directed to processes for the production of the fragments according to claims 1 to 7, claims 10, 11 (partly), 12 to 14 were directed to DNA vectors comprising a DNA fragment encoding H2-relaxin.

In items 6-9 of the Reasons for the Decision, the Board of Appeal considered several arguments that were raised by opponents and discussed in detail during the opposition to the patent including the arguments that the claimed subject matter already existed in nature; was a discovery as opposite to an invention; was contrary to ordre public; offended human dignity and was tantamount to patenting human life. The Board dismissed each of these objections and maintained the above claim as granted in a form which is clearly not restricted by any purpose or functional limitation. The Board stated in points 6-9 of the decision:

6. The Appellants argued that the subject-matter of product claims 2 to 7, 10 to 14 and 18 to 21 fell within the category of exceptions to patentability or must be considered as a discovery of biological elements present in the human body which may not be patented.

7. To assess the validity of these arguments, Articles 53(a) and 52(2)(a) EPC are interpreted by the Board in accordance with the implementing Rules 23(d) and 23(e)(2)EPC. Rule 23(d) provides a list of processes and uses which are exceptions to patentability but does not mention any products. However, it is a non-exhaustive list, which implies that product claims relating to biological material may equally be found unallowable under Article 53 a) EPC. Rule 23(e)(2), however, defines which biological material originating from the human body may be patented. It states that:

"(2) An element isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequence of a gene may constitute a patentable invention, even if the structure of that element is identical to that of a natural element".

It follows from the text itself that the matter mentioned above is not to be considered as an exception to patentability under Article 53(a) EPC. Claims 2 to 7, 10 to 14 and 18 to 21 are, thus, allowable under this article.

8. Claims 2 to 7, 10 to 14 and 18 to 21 directly or indirectly relate to DNAs encoding the human protein preprorelaxin or to the human preprorelaxin per se, which are described in the patent in suit on pages 9 to 15 as having been obtained by technical processes. They, thus, answer the definition of patentable elements of the human body given in Rule 23(e)(2) EPC. Accordingly, they do not fall within the category of inventions which may not be patented for being discoveries (Article 52(2)(a) EPC).

9. Thus, the Appellants' arguments under Articles 53(a) and 52(2)(a) EPC (see section IV and XII, supra) are answered by the new implementing Rules 23(d) and 23(e) EPC.

This decision was issued in 2002 and considered the amendments to the European Patent Convention incorporating the content of the Biotech Directive 98/44/EC as current Rules 26-29 EPC. It should be mentioned here that ethical objections were raised before the Directive was enacted. Such objections were discussed at length within the context of the Directive, before the final compromise was adopted. Some of the arguments were therefore to an extent moot by the time the Board of Appeal took Decision T 272/95.

In the 1990's, the wholesale sequencing of random fragments of expressed genes from cDNA libraries (Expressed Sequence Tags or ESTs) whose function was unknown and attempts to patent such nucleic acids sequences without providing a known function of said sequences continued to fuel this controversy. Such applications that simply provide DNA sequences without providing any function of these sequences generally do not meet the requirements of industrial applicability or inventive step because without a function the skilled person would not know how to use such sequences or would consider trial use of the sequences as obvious¹⁸⁶.

Nevertheless, a "grey zone" currently exists between those patent applications that clearly meet the requirements of industrial applicability/inventive step and those patent applications where these patentability requirements are questionable. Within this "grey zone" are situations, for example, in which inventors have filed patent applications claiming DNA molecules with known sequence where the function of the expressed protein has been speculated upon without providing (enough) concrete experimental evidence in the application that the particular DNA does indeed encode for a protein with the alleged function. In such cases, the EPO examines these patents/patent applications on an individual basis because the facts of the case vary and patentability depends on the scientific facts. The question that is typically examined is whether the inventor has made plausible (or credible) that the claimed invention meets the requirements of patentability based on the disclosure in the application as originally filed. Examples of decisions of the Technical Board of Appeal at the EPO involving such cases are T604/04; T870/04; T1329/04; T898/05; T1165/06; T1452/06; and T18/09. According to T870/04, "The purpose of granting a patent is not to reserve an unexplored field of research to an applicant".

¹⁸⁶ Roberts, L (1991). "Genome patent fight erupts: an NIH plan to patent thousands of random DNA sequences will discourage industrial investment and undercut the Genome Project itself, the plan's critics charge". Science 254 (5029): 184-186.

Finally, a more recent set of patents¹⁸⁷ relating to the human BRCA1 gene have attracted some attention. Certain mutations in the BRCA1 gene have been found to correlate with an increased risk of development of breast and ovarian cancer in humans. Opposition/appeal proceedings at the EPO were initiated by several non-commercial and commercial entities against these patents. The decision of the Board of Appeal in T1213/05 which relates to EP 705 902 is discussed below since historically the opposition and appeal case were heard at the EPO after the transposition of the Biotech Directive by the various Member States of the EU.

4 Biotechnology Directive 98/44/EC

Directive 98/44/EC includes a preamble and two Chapters of particular interest to this report on the scope of protection of nucleic acid related claims: Chapter I regulates the patentability of biotechnological inventions and Chapter II deals with the scope of protection of such inventions.

Important passages from these sections of the Directive are as follows:

4.1 Preamble

Items 20 to 25 of the Preamble to the Directive relate to considerations on the patentability (or exclusion thereof) of the human body and in particular nucleic acid sequences encoding genes:

(20) Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment;

(21) Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself;

(22) Whereas the discussion on the patentability of sequences or partial sequences of genes is controversial; whereas, according to this Directive, the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application; whereas the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed;

(23) Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;

¹⁸⁷ EP 705 903 and EP 705 902

(24) Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs;

(25) Whereas, for the purposes of interpreting rights conferred by a patent, when sequences overlap only in parts which are not essential to the invention, each sequence will be considered as an independent sequence in patent law terms.

Item 46 relates to the extension of patent protection for self-reproducing material:

(46) Whereas, in view of the fact that the function of a patent is to reward the inventor for his creative efforts by granting an exclusive but time-bound right, and thereby encourage inventive activities, the holder of the patent should be entitled to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the use of patented, non-self-reproducing products, that is to say the production of the patented product itself.

4.2 Chapter I: Patentability

Article 2

1. For the purposes of this Directive,

(a) 'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;...

Article 3

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

4.3 Chapter II: Scope of Protection

Article 9

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.

4.4 National Law Implementation of the Biotech Directive

This section provides an overview of the transposition of the Biotech Directive in those Member States which have seemingly not followed the transposition approach of all remaining Member States.

Most of the countries of the European Union have transposed the Biotech Directive into national legislation using the explicit or essentially identical wording used in the Directive. In this regard, a recent survey made in 2016 by the epi Biotech Committee (epi is the Institute of Professional Representatives before the European Patent Office) is included as Annex 1¹⁸⁸. Nevertheless, some countries transposed the Directive using language which is not directly found and goes beyond that in the Directive. Notable examples of this are the Germany, France, Italy, Poland and Luxembourg.

This non-unified transposition may question the goal of harmonization in the Directive (see Recitals 3-7). Moreover, there seems to be some inconsistency or lack of clarity as to how the transposed provisions of the Directive, once implemented, are to be applied. This is of particular concern with

¹⁸⁸ The contributions regarding the national laws have been made by epi members of the Biotech Committee and by epi Board members.

regard to the scope of protection permitted in the various EU countries for genetic elements originating from humans.

In this context, reference should also be made to a resolution by the European Parliament in 2001 which reaffirmed a previous resolution from the year 2000, demanding: “to adopt the measures required to ensure that the human genetic code is freely available for research throughout the world and that medical applications of certain human genes are not impeded by means of monopolies based on patents.”¹⁸⁹ This position of the European Parliament again was reaffirmed in a resolution in the year 2005 which reads: “Calls on the European Patent Office and the Member States to grant patents on human DNA only in connection with a concrete application and for the scope of the patent to be limited to this concrete application so that other users can use and patent the same DNA sequence for other applications (purpose-bound protection).”¹⁹⁰

4.4.1 German Law

§1(a) of the German Patent Act (“Patentgesetz”; PatG)¹⁹¹ incorporates Article 5 of the Biotech Directive as follows:

Section 1a

(1) The human body at its various stages of formation and development, including germ cells, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute a patentable invention.

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention even if the structure of that element is identical to that of a natural element.

(3) The industrial application of a sequence or a partial sequence of a gene shall have to be specifically disclosed in the application by indicating the function fulfilled by the sequence or partial sequence.

(4) Where the subject matter of an invention is a sequence or a partial sequence of a gene, the structure of which is identical to the structure of a natural sequence or partial sequence of a human gene, **the use thereof, for which industrial application is specifically described in subsection (3), shall have to be included in the patent claim**¹⁹².

¹⁸⁹ European Parliament resolution on the patenting of BRCA1 and BRCA2 (‘breast cancer’) genes, www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+MOTION+P5-RC-2001-0633+0+DOC+XML+V0//EN&language=cs

¹⁹⁰ European Parliament resolution on patents for biotechnological inventions www.europarl.europa.eu/sides/getDoc.do?sessionId=3CEC3F2B9A6DB6F08C3C22BFF958CBFE.node2?pubRef=-//EP//TEXT+TA+P6-TA-2005-0407+0+DOC+XML+V0//EN

¹⁹¹ <http://www.wipo.int/edocs/lexdocs/laws/en/de/de116en.pdf>

¹⁹² The bold-faced type above indicates that part of the law which does not find a counterpart in the Biotech Directive.

In addition, the German Ministry of Justice officially issued a Statement of Grounds as explanatory note to the law which was confirmed by the Legal Committee of the German Parliament (Article 15/4417, 1.12.2004) and which stated the following:

With regard to 2 (Article 1 Nr. 2, § 1a. 4 – new – draft Patent Act)

New paragraph 4 restricts the scope of protection of genes and gene sequences that correspond to human genes and gene sequences to the use described in the patent claim. An invention in connection with a novel use of the gene that is not contained in the patent claim does not lead in this case to a dependent patent. A license from the first inventor is not necessary. Thus, in the future there is no longer absolute product protection for genes, gene sequences and/or partial gene sequences whose structure matches with the structure of a human gene, i.e. a gene that is also present in humans. Rather, the scope of protection is limited to the use described in the patent claim. In order to attain this goal, the disclosed use must be taken up in the patent claim because the protective scope of the patent is determined by the content of the patent claims (§14 Patent Act). ...In this context, it should be mentioned that the patent examiner as a consequence of the new rule in § 1a Abs. 3 must limit the patent to the part of the gene in the application that is essential (“relevant for function”), but must remove gene fragments from the scope of protection that are not necessary for the function. The legal situation remains unchanged with regard to genes and gene sequences that do not match with human genes. However, because of the technical progress in the decoding of human genes, for instance by use of sequencing machines, in the sector of plants and animals de facto only very rarely will absolute protection be granted for genes. As a rule, inventive step will not be present.

While the contents of this document are not law, they may be used by a German Court when determining how to interpret §1(a)(4) of the German Patent Act.¹⁹³

In 2007 the German Patent Office (DPMA) mentioned five examples of German national patent applications with claims concerning DNA molecules that had gone to grant after implementation of the new version of §1(a)(4)¹⁹⁴. The patent claims from these five examples, namely DE 103 06 085 B4, DE 102 41 553 B4, DE 199 58 198 B4, DE 10 2004 004 924 B4 and DE 199 55 576 B4, are provided in Annex 4 and are interesting because they all contain a use within the meaning of §1(a)(4), i.e. “for detection of...”, “for diagnosis of”, “for detection of...”, “for use in the diagnosis of...” and “for use as a medicament”, respectively. However, two of the claims contain the language “**capable** of being used for the diagnosis of...” and “which is **suitable** for detection...”. This language explicitly states that the subject matter must simply be capable or suitable to do perform a function, but is not limited thereto.

Based on this relatively small sample of claims, it seems that the German Patent Office has applied the Biotech Directive with the additional requirement of describing the use of the nucleic acid in the claim without having to explicitly restrict the claim to that particular use because some granted claims contain “capable of” or “suitable for” language.

¹⁹³ Kraßer 2004: Patentrecht, 5th edition: pp. 220–234.

¹⁹⁴ Das Europäische Patentsystem. Wandel von Governance durch Parlamente und Zivilgesellschaft, I. Schneider, Frankfurt am Main/New York: Campus 2010, in particular pages 636-638

Hence, it seems that transposition of the Biotech Directive is not being consistently interpreted by the DPMA to mean that claims directed to nucleic acids have to be explicitly restricted in their language to the industrial applicability that is given in the application for those nucleic acids. Whether such claims, in which the use is formulated using non-restrictive “capable of” or “suitable for” language, will be upheld by the German Courts remains to be tested.

A further issue arising from the alternative transposition of the Biotech Directive in Germany is caused by the different requirements of patentability imposed by the German Patent Act in comparison to the EPC. While a claim to a nucleic acid encoding a human gene stemming from a German national patent might be invalidated for failure to comply with §1(a)(4) of the German Patent Act by not including the function for which the industrial application of the nucleic acid is based in the claim, this cannot be the case for a claim to the same nucleic acid encoding a human gene stemming from a European Patent which is validated in Germany. The reason for this is that Article 138 EPC provides an exhaustive list (“...may be revoked with effect for a Contracting State **only** on the grounds...”¹⁹⁵) for reasons for the revocation of European patents that does not include failure to include the function for which the industrial application of the nucleic acid is based in the claim.

In a recent case (X ZR 141/13), the German Supreme Court has to decide on the validity of a German patent stemming from European patent EP 959 132 B1 with a claim to a nucleic acid sequence that related to a human genomic DNA and did not have a purpose limitation in the claim. The Supreme Court decided that such a claim was patentable in view of § 1a of the German Patent Act (and Rule 29 of the EPC). For a discussion of the reasons put forth by the Court in its decision, see section 5.8.2 below.

It remains to be seen whether a German Court would interpret §1(a)(4) of the German Patent Act to restrict the scope of protection of a nucleic acid claim that stems from a European patent and does not contain a particular function to a function that is mentioned in the specification (see Annex 4 for further explanation).

4.4.2 French Law

The situation in France is somewhat different and more restrictive.

Article L 611-18 of The Intellectual Property Code of France¹⁹⁵ states that:

The human body, at the different stages of its constitution and its development, and also the simple discovery of one of its elements, including the total or partial sequence of a gene, may not constitute patentable inventions. Only an invention constituting the technical application of a function of an element of the human body may be patent-protected. This protection covers the element of the human body only to the extent necessary for carrying out and working this particular application. Such application must be detailed in specific and precise terms in the patent application. The following shall, inter alia, not be patentable: (a) processes for cloning of human beings; (b) processes for modifying the genetic identity of

¹⁹⁵ <http://www.wipo.int/scp/en/exceptions/replies/france.html#Q11>

*human beings; (c) the uses of human embryos for industrial or commercial purposes; (d) the total or partial sequences of a gene taken as such*¹⁹⁶.

Moreover, the French legislator included stricter provisions while transposing the Biotech Directive in Article L 613-2-1 of Code de la Propriété Intellectuelle which specifies that:

The scope of a claim concerning a gene sequence shall be confined to the part of such sequence that is directly related to the specific function disclosed concretely in the description. The rights created by the delivery of a patent including a gene sequence may not be called upon against a later claim on the same sequence if this claim satisfies the requirements of Article L. 611-18 and if it discloses any other particular application of this sequence.

Article L 613-2-2 states:

Save as provided in Articles L. 613-2-1 and L. 611-18, the protection conferred by a patent on a product containing or consisting of genetic information shall extend to any material in which the product is incorporated and in which the genetic information is contained and performs its stated function.

It seems that the French law has explicitly provided for a limitation in Article L 611-18 and L 613-2-1 in the scope of protection of a claim reciting a gene as well as a moratorium on the patenting of genes per se which, however, may be restricted to human genes.

The alternative text in the French law raises similar issues as mentioned above with regard to the deviation in §1(a)(4) of the German Patent Act and Article 138 EPC.

4.4.3 Luxembourg Law

The situation in Luxembourg is also different from Germany and France. The law in Luxembourg was changed in in 2006 as follows.

Article 5ter

1) The human body, at the various stages of its formation and development, including germ cells, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2) An isolated element of the human body or otherwise produced by a technical process, including the sequence or the partial sequence of a gene, can constitute a patentable invention, even if the structure of this element is identical to that of a natural element.

3) Only an invention constituting a technical application of a function of an element of the human body may be protected by a patent. This protection shall cover the element of the human body only to the extent necessary to the realization and the exploitation of this particular use. Such use must be disclosed in the patent application in a concrete and precise manner.

¹⁹⁶ The bold-faced type above indicates that part of the law which does not find a counterpart in the Biotech Directive.

The alternative text in the Luxembourg law raises similar issues as mentioned above with regard to the deviation in §1(a)(4) of the German Patent Act and Article 138 EPC.

4.4.4 Italian Law

The Decree-Law No. 3 transposing Directive 98/44/EC on the legal protection of biotechnological inventions provides that the function and industrial application of an isolated element of the human body must be indicated concretely described and specifically claimed in the patent application. The text of the Decree is reflected in Article 81 of the Italian Code of Industrial Property which is provided below (source: <http://www.wipo.int/edocs/lexdocs/laws/en/it/it204en.pdf>):

81-4. Patentability.

1. The following may be patented provided that they meet the requirements of novelty and inventive activity and are susceptible to industrial application:

- a) a biological material, isolated from its natural environment or produced through a technical process, even if pre-existing in a natural state;
- b) a technical process through which biological material is produced, processed or used, even if pre-existing in a natural state;
- c) any new utilization of a biological material or of a technical process relating to biological material;
- d) an invention relating to an element isolated from the human body or produced otherwise, through a technical process, even if its structure is identical to that of a natural element, provided that its function and industrial application are concretely indicated and described. A technical process is understood as that which only human beings are capable of carrying out and that nature by itself is not able to perform;

81-5. Exclusions.

1. Subject to the exclusions set forth in Article 45(4), the following may not be patented:

- a) the human body, from the moment of conception and in the various stages of its development, nor the mere discovery of one of the elements of the body itself, **including the sequence or partial sequence of a gene**, in order to guarantee that patenting rights are exercised with respect for the fundamental rights and integrity of man and the environment;
- b) ...
- c) **a simple DNA sequence, a partial sequence of a gene, used to produce a protein or a partial protein, unless** an indication and description is provided of a **function useful for evaluation of the requirement of industrial application and the corresponding function has**

been specifically claimed; each sequence is considered independent for patent purposes in the event of sequences that overlap only in the parts not essential to the invention¹⁹⁷.

The alternative text in Italian law vis-à-vis the Biotech Directive raise similar issues as mentioned above with regard to the deviations in the German, French and Luxembourg laws and Article 138 EPC.

4.4.5 Polish Law

According to Article 93 of the Polish Industrial property Law:

1. ...

2. In a patent application concerning a sequence or a partial sequence of a gene, the industrial application of the sequence must be disclosed in the patent description, **and additionally its function is to be indicated in the independent patent claim.**

3. In order to fulfil the industrial applicability criterion in a case of use of a sequence or a partial sequence of a gene for production of a protein or a protein part, it is to be defined in the description of the invention which protein or protein part thereof is produced and what is their function.

The alternative text in Polish law vis-à-vis the Biotech Directive raise similar issues as mentioned above with regard to the deviations in the German, French, Italian and Luxembourg laws and Article 138 EPC.

4.5 European Patent Convention

While not being bound by the Directive, the Administrative Council of the European Patent Office amended the Implementing Regulations of the European Patent Convention to incorporate the above principles on patentability in the following:

Rule 27 Patentable biotechnological inventions

Biotechnological inventions shall also be patentable if they concern:

- (a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;...

Rule 28...

¹⁹⁷ The bold-faced type above indicates that part of the law which does not find a counterpart in the Biotech Directive.

Rule 29 The human body and its elements

- (1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
- (2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
- (3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

The EPC does not contain a counterpart to Article 9 of the Directive. It does however contain Article 69 on the extent of protection of a European patent:

Article 69 Extent of protection

- (1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

The original purpose of Article 69 EPC was to insure that the scope of patent claims is to be determined during proceedings before the EPO in light of the patent description and not by exclusively reading the claims on their own, irrespective of what is disclosed in the specification. This article does not deal directly with the issue of absolute product protection versus purpose-limited protection, even though it could be of indirect influence. Under a number of jurisdictions, Art. 69 EPC is the basis for construing the claim with a view to determining the scope of the invention claimed. In that regard, the concept of purpose or function limited product protection could come into play, even though this limitation would normally be governed by a separate statutory provision, or be part of the provisions regarding the scope of the exclusive right.

One important decision of the Technical Board of Appeal of the EPO with regard to Rule 29(3) of the EPC (and Article 5(3) of the Biotech Directive) is T898/05. This decision discusses the function of a protein and the gene encoding said protein and describes what particular functions are required to fulfil the requirements of industrial applicability (Article 57 EPC).

Item 1 in the Reasons for the Decision states:

1. According to Article 52(1) EPC for a European patent to be granted an invention has to satisfy inter alia the requirement of being "susceptible of industrial application". According to Article 57 EPC, this requirement is fulfilled if the invention "can be made or used in any kind of industry, including agriculture". In this respect, Rule 27(1)(f) EPC prescribes that the description should "indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry." Rule 23e(3) EPC, which relates to biotechnological inventions, similarly requires that "the

industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application".

Rule 23e(3) EPC 1997 is now Rule 29(3) EPC 2000.

After deliberating these points, the Board penned the following headnote to the decision:

3. The function of a protein (and thus of the nucleic acid encoding it) can be seen at different levels, which include its molecular function, its cellular function and its biological function in a broad sense. The elucidation of one of these particular levels of function might result, under certain conditions, in a straightforward industrial application, even though the other levels of activity remain completely unknown or only partially characterized. For the purpose of Article 57 EPC and Rules 23e(3) and 27(1)(f) EPC, none of these levels is more fundamental than the other ones insofar as at least from one of these levels a practical application (a profitable use in a wider sense) is derivable in a straightforward manner (cf. points 29 and 30 of the Reasons).

Other interesting cases of the Technical Board of Appeal of the EPO with regard to the borders of an acceptable disclosure concerning biotechnology inventions and industrial application are T604/04; T870/04; T1329/04; and T1165/06; T1452/06; and T18/09.

Finally, as mentioned above, EP 705 902, which relates to the human BRCA1 and the fact that certain mutations in this gene have been found to correlate with an increased risk of development of breast and ovarian cancer in humans is of interest. This patent was opposed by several non-commercial and commercial entities including doctors associations, research institutions and Greenpeace. Many of the grounds for opposition were based on concerns which are closely related to the scope of DNA-related inventions: Myriad Genetics, Inc. was granted several patents for the breast cancer gene BRCA 1 and 2 by the EPO. In the patents on BRCA 1 (EP 705 903, EP 0705 902), Myriad claimed about 80 human gene segments of different lengths (EP 905 903) and diagnostic methods using these mutations that are typical of hereditary breast cancer. EP 905 903 contains claims to the wild-type human gene and the use of the gene for gene therapy as well as a kit for detecting mutations. Claims 1 and 2 of EP 0705 902 which were considered during the appeal (T1213/05) were:

1. A nucleic acid probe wherein the nucleotide sequence of said probe comprises the following DNA sequence:

AG GAA ...A

or a DNA probe comprising a nucleotide sequence selected from the group consisting of SEQ ID NOs: 35, 38, 41, 42, 47, 57, 62, 66, 67, 72 and 81.

2. A replicative cloning vector which comprises (a) an isolated DNA according to claim 1 and (b) a replicon operative in a host cell for said vector.

The oppositions in this case included grounds that the sequences of the claims occur in nature and are therefore a discovery rather than an invention and are therefore not patentable inventions at all according to Article 52(2) EPC. In addition, one of the opponents objected under Article 53(a) EPC. Its arguments were summarized by the Board of Appeal in point 45 of decision T 1213/05:

52. Opponent 02 argued that the socio-economic consequences of the patenting of the claimed subject-matter should be considered by the Board under Article 53(a) EPC, because in the present case, these consequences touched ethical issues. Patenting of the claimed subject-matter would not only result in increased costs for patients, but would also influence the way in which diagnosis and research would be organized in Europe, which would be clearly to the detriment of patients and doctors. The fact that a particular group of patients, i.e. patients suspected to carry a predisposition to breast cancer, would be faced with severe disadvantages and would become dependent on the patent proprietor, was contrary to human dignity. Therefore, the claimed subject-matter constituted an exception to patentability under Article 53(a) EPC.

The patentee was considered by some to be overextending its monopoly position by only licencing its technology to a very limited set of laboratories and was charging what some considered exorbitant prices for having the tests conducted. Another point of contention was that Myriad was collecting data obtained by the tests on further mutations in the BRCA genes and preventing those who conducted the test from disseminating this data. However, it is noted here that any alleged abuse of a patent position is a matter of competition law and not patent law per se.

During the appeal, opponent 2 argued that the implementation of the Directive in the national law of France and Germany had made it clear that socio-economic and ethical concerns about the patenting of human genes had to be taken into account. The French legislator had explicitly provided that not genes as such, but only functions derived from genes should be patentable, and the German legislator had provided a separate legislation for the patenting of human genes in view of ethical concerns.

Thus, in contrast to the decision T272/95 (relaxin), mentioned above in section 3, this decision of the Board of Appeal in T1213/05 directly commented on the fact that several Contracting States of the EPC including German and France have transposed the Directive with alternative language. The Board also commented in this context on the resolution of the European Parliament from 2005 as mentioned above. Points 54/55 of this decision states:

55. Opponent 02 therefore seems to imply that the correct implementation of the Directive requires the importation of socio-economic concerns into the text of the Directive, upon the basis that certain EU Member States have adopted this approach to implementing the Directive.

The Board does not agree with this position. The content of national legislation does not form part of the legal order established by the EPC and is thus irrelevant to the issue of how the EPC should be interpreted.

Opponent 02 also referred to the resolution of the European Parliament, P6_TA(2005)0407 of 26 October 2005 "Patents on biotechnological inventions" ("the Resolution"). Opponent 02 argued that the Resolution could be used to interpret the Directive and thus introduce socio-economic and ethical issues into the EPO's patent granting process.

Opponent 02 referred in the Oral Proceedings, in particular, to recitals J and L and paragraphs 4 and 5 of the Resolution. These state:

"J. whereas the Directive allows the patenting of human DNA only in connection with a function, but it is unclear whether a patent on DNA covers only the application in this function or whether other functions are also covered by the patent,

L. whereas over-generous granting of patents can stifle innovation,

4. Considers that the Directive provides the framework for this in most cases, but that it still leaves important questions open, such as the patenting of human DNA;

5. Calls on the European Patent Office and the Member States to grant patents on human DNA only in connection with a concrete application and for the scope of the patent to be limited to this concrete application so that other users can use and patent the same DNA sequence for other applications (purpose-bound protection)".

Recitals J, L and paragraph 4, can be considered as general statements of fact and/or opinion. Paragraph 5 is the only part of the Resolution relied on by Opponent 02 that calls for action on the part of the EPO. The wording of paragraph 5 contains no suggestion that the EPO has been, or should be, vested with the task of taking into account the socio-economic effects of the grant of patents in specific areas and restricting the field of patentable subject-matter accordingly. Thus the Resolution provides no support for Opponent 02's already rejected objection under Article 53(a) EPC (see point (53) above), or for any further objection based upon some general duty to take into account the socio-economic effects of the grant of patents in specific areas and to restrict the field of patentable subject-matter accordingly.

The decision in T1213/05 was handed down in 2007.

5 CJEU Decision C-428/08 Monsanto

In 2010 the Court of Justice of the European Union (CJEU) rendered a judgement on the interpretation of the Biotechnology Directive 98/44/EC in case C-428/08. This case revolved around the patentee's attempt to enforce a nationalized European patent having claims to isolated DNA molecules, methods of producing genetically transformed plants which are tolerant toward herbicide and herbicide tolerant plant cells comprising the aforementioned DNA. The CJEU was requested by the referring Dutch Court to provide answers to three specific questions that addressed the meaning of Article 9 of the Directive in relation to the subject matter of the patent and one specific question related to relationship of the Directive to Articles 27 and 30 of the international Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

While the CJEU provided answers to all four of these questions, the decision in this precedential case has been given several different interpretations by various parties.

Whereas some parties have interpreted the reasoning of the decision as a proclamation extinguishing absolute product protection for genes and DNA, others have expressed the view that this decision is extremely fact related and that the conclusions drawn cannot be generally applied¹⁹⁸.

This section of the report summarizes the patented technology, the factual circumstances surrounding the alleged infringement of the patent and the reasoning of the decision.

5.1 Patented Technology

Monsanto Company was granted European patent EP 0 546 090 relating to ‘Glyphosate tolerant 5-enolpyruvylshikimate-3-phosphate synthases’. Glyphosate is a broad spectrum herbicide. It inhibits the enzyme 5-enol-pyruvylshikimate-3-phosphate synthase (also called ‘EPSPS’), which is needed for plant growth. Treatment of a plant with glyphosate results in the inhibition of the glyphosate-sensitive EPSPS enzyme and plant death. Monsanto’s patent describes a type of bacterial EPSPS enzyme which is not sensitive to glyphosate as well as the DNA sequence encoding the enzyme. Monsanto inserted the gene encoding the bacterial EPSPS enzyme into the DNA of a soy plant. As a result, the genetically modified soy plant produces a glyphosate-resistant EPSPS enzyme. Since the genetically engineered plants are resistant to the glyphosate, they survive glyphosate treatment, whereas sensitive plants such as weeds are destroyed. (For a pictorial summary of the invention see Annex 2).

The claims of EP 0 546 090 are essentially directed to an isolated DNA sequence encoding a Class II EPSPS enzyme (claim 1); an isolated DNA sequence encoding a protein which exhibits EPSPS activity (claim 4); a recombinant, double-stranded DNA molecule comprising a promoter and a DNA sequence encoding a Class II EPSPS enzyme (claim 7); a method of producing genetically transformed plants which are tolerant toward glyphosate herbicide using a recombinant, double-stranded DNA molecule comprising a promoter and a DNA sequence encoding a Class II EPSPS enzyme (claim 14); and a glyphosate tolerant plant cell comprising such DNA molecules (claim 20); and a method for selectively controlling weeds in a field with plants that are glyphosate tolerant as a result of the expression of such DNA sequences and applying to said crop and weeds in said field a sufficient amount of glyphosate herbicide to control said weeds without significantly affecting said crop (claim 28) (The exact wording for the independent claims of EP 0 546 090 are provided in Annex 3).

It should be noted that the claim set of EP 0 546 090 does not contain a claim to soymeal or any other processed product stemming from soy beans, nor to plants comprising DNA encoding a Class II EPSPS enzyme.

¹⁹⁸ Constructing European Intellectual Property: Achievements and New Perspectives, C. Geiger, Ed., Edward Elgar Publ., UK, p. 265ff. (2013); Intellectual Property and Genetically Modified Organisms: A Convergence in Laws, Lawson and Charnley, Eds., Ashgate Publ. UK, p. 37 (2015); European Intellectual Property Law: Text, Cases and Materials, Kur and Dreier, Eds., Edward Elgar Publ., UK, p. 135 ff. (2013) as well as M. Lamping in EJRR 4: 445-450, m 2010 and G. van Overwalle in IIC 1-3, 2011

5.2 Factual Situation

The soy seeds that Monsanto sells that utilize the patented technology are known commercially as “Round-up Ready”[®] soy. This name comes from the fact that the herbicide glyphosate is sold by Monsanto as “Round-up”[®], and the genetically altered plants are “ready” to be treated with the herbicide Round-up[®]. Round-up Ready[®] soy is grown on a large scale in South America. However, there is no patent protection for the Monsanto invention in Argentina.

In the summer of 2005 several cargos of soy meal from Argentina that were suspected of originating from Round-up Ready[®] soybean reached the port of Amsterdam and were detained by the customs authorities. They were released after Monsanto had taken samples.

Monsanto tested the samples to determine whether they originated from RR soybeans.

Tests on the samples revealed the presence of the full DNA sequence encoding bacterial EPSPS enzyme in the soy meal. As a result, Monsanto requested an injunction before the Rechtbank’s-Gravenhage, on the basis of infringement of the European patent.

After hearing the evidence, the Rechtbank’s-Gravenhage considered that Monsanto established the presence of the DNA sequence protected by its European patent in the soy meal.

According to Article 53(1) of the Dutch Patent Act:

1. Subject to the provisions contained in Articles 54 to 60, a patent shall confer on its owner the exclusive right:
 - a. to make, use, put on the market or resell, hire out or deliver the patented product, or otherwise deal in it in or for his business, or to offer, import or stock it for any of those purposes;
 - b. to use the patented process in or for his business or to use, put on the market, or resell, hire out or deliver the product obtained directly as a result of the use of the patented process, or otherwise deal in it in or for his business, or to offer, import or stock it for any of those purposes.

Hence, the Court could have applied Article 53(1) of the Dutch Patent Act to determine that the importation of soy meal containing the full length sequence encoding the bacterial EPSPS enzyme was an infringing act.

However, instead the Dutch Court turned to Article 53/53a of the Dutch Patent Law, which reads:

1. In respect of a patent on a biological material possessing specific characteristics as a result of the invention, the exclusive right shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
2. In respect of a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention, the exclusive right shall extend

to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

3. In respect of a patent on a product containing or consisting of genetic information, the exclusive right shall extend to all material in which the product is incorporated and in which the genetic information is contained and performs its function.

The Dutch Court recognized that the soy meal was “dead material” and that the gene encoding the bacterial EPSPS enzyme could not perform its function in this dead material. Nevertheless, the Court was uncertain as to whether that presence of the DNA encoding the bacterial EPSPS enzyme in the soy meal alone was sufficient to constitute infringement of Monsanto’s European patent.

The Dutch Court stated:

30 If the trade in the soy meal cannot be opposed on the basis of Article 53a(3) of the 1995 Law, which transposes Article 9 of the Directive, it then becomes relevant to ask whether classic, absolute protection such as that provided for by Article 53 of the 1995 Law could be relied on.

31 In that regard, it would appear that the Directive does not detract from the absolute product protection conferred by a provision such as Article 53 of the 1995 Law, but rather strives for minimum protection. However, the indicia supporting such an interpretation are not sufficiently clear.

5.3 Questions posed to the CJEU

In that context, the Rechtbank’s-Gravenhage decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

1. Must Article 9 of Directive 98/44/EC ... be interpreted as meaning that the protection provided under that provision can be invoked even in a situation such as that in the present proceedings, in which the product (the DNA sequence) forms part of a material imported into the European Union (soy meal) and does not perform its function at the time of the alleged infringement, but has indeed performed its function (in the soy plant) or would possibly again be able to perform its function after it has been isolated from that material and inserted into the cell of an organism?
2. Proceeding on the basis that the DNA sequence described in claim 6 of patent No EP 0 546 090 is present in the soy meal imported into the Community by Cefetra and [Toepfer], and that the DNA is incorporated in the soy meal for the purposes of Article 9 of [the Directive] and that it does not perform its function therein: does the protection of a patent on biological material as provided for under [the Directive], in particular under Article 9 thereof, preclude the national patent legislation from offering (in parallel) absolute protection to the product (the DNA) as such, regardless of whether

that DNA performs its function, and must the protection as provided under Article 9 of [the Directive] therefore be deemed to be exhaustive in the situation referred to in that provision, in which the product consists in genetic information or contains such information, and the product is incorporated in material which contains the genetic information?

3. Does it make any difference, for the purpose of answering the previous question, that patent No EP 0 546 090 was applied for and granted (on 19 June 1996) prior to the adoption of [the Directive] and that such absolute product protection was granted under national patent legislation prior to the adoption of that directive?
4. Is it possible, in answering the previous questions, to take into consideration the TRIPS Agreement, in particular Articles 27 and 30 thereof?

5.4 Answer of the CJEU to Question 1

The Court answered Question 1 as follows:

1. Article 9 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions is to be interpreted as not conferring patent right protection in circumstances such as those of the case in the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function for which it is patented, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform that function after it had been extracted from the soy meal and inserted into the cell of a living organism.

The reasoning for this decision is based in part in items 40, 48 and 49 of the decision:

40. To allow protection under Article 9 of the Directive on the ground that the genetic information performed its function previously in the material containing it or that it could possibly perform that function again in another material would amount to depriving the provision interpreted of its effectiveness, since one or other of those situations could, in principle, always be relied on.

48. As follows from paragraph 37 of this judgment, a DNA sequence such as that at issue in the main proceedings is not able to perform its function when it is incorporated in a dead material such as soy meal.

49. Such a sequence does not, therefore, enjoy patent right protection, since neither Article 9 of the Directive nor any other provision thereof accords protection to a patented DNA sequence which is not able to perform its function.

Based on the facts of the case, all Experts agree that the reasoning by the Court is in principle correct because the Court seems to have considered the existence of the full-length gene encoding the bacterial EPSPS enzyme in the soy meal as an “artefact” which did not contribute any particular attribute to the soy meal per se.

Nevertheless, in item 40 of the decision, the Court seems to have relied heavily on the explicit wording of Article 9 with regard to the present tense use in the phrase “performs its function” because it thought that this expression would be rendered meaningless if it were to be expanded to include past or future possibilities.

Several (3/15) Experts were of the opinion that the phrase “performs its function” in Article 9 has been correctly interpreted by the CJEU in the case at issue and fully agree with the considerations of the court outlined in point 40 of the decision.

However, the majority of the (11/15) Experts are of the view that a generalization of this literal, temporally restricted interpretation of the term “performs its function” by the Court and any application to future cases involving the scope of protection of DNA per se creates a practical dilemma from a scientific perspective and is problematic.

In order to illustrate this dilemma one expert mentioned the following example:

A patentee might have a claim to an isolated DNA molecule comprising non-human regulatory DNA for expressing a human gene encoding a certain protein, wherein the intended use is to express the gene in a cell system in vitro or to act as a probe in a diagnostic kit, for example. Typically, such DNA fragments are sold in dry (lyophilized) form (for use as an expression tool) or attached to a solid substrate (such as a chip or plastic plate for use in a diagnostic test) because DNA is far more stable during shipping and storage in this dry form. In both cases, the isolated DNA cannot “perform its function” because the DNA is sold in a dry state, although in both cases the DNA is “capable of performing its function” if put in an aqueous environment with the appropriate reagents necessary for it to function to express the gene or be useful as a diagnostic probe. If one were to generalize the logic of the Court and apply the literal interpretation of “perform its function”, this would have the consequence that a patentee with a claim to such a DNA molecule could no longer successfully enforce said claim against an alleged infringer who stores, offers, sells or offers to sell such a dry DNA because the DNA does not “perform” its function, even though it is capable of performing its function when placed in the correct environment.

Some (3/15) of the Experts were of the opinion that this example is not helpful in this context, since the Court did not discuss a case where the DNA derived from the plants would have been re-inserted in another organism or commercialized in a lyophilized form. While the DNA was still present in the soy meal in the Monsanto case, it did not have any commercial or any function value anymore. However in the example of the lyophilized DNA, the DNA is frozen with the intention to preserve its function. Thus for the opinion of the expert, the Monsanto case and the example should not be mixed up when discussing the legal implications. Another expert considered that a similar situation occurs with many chemicals that are sold in a state, dry for instance, where they cannot perform their function and have to be put in another state, dissolved, for instance to do so.

A minority of Experts mentioned the example of patented elements in plant varieties, or in other words, the situation where a patent on an invention (for example a DNA sequence encoding for a certain protein or characteristic) covers also plant varieties in its scope. When such plant varieties are used for further breeding, it may happen that following several crosses in a breeding program originally functional DNA sequences constituting the patented invention are still present in the final, newly developed and commercialized plant variety without expressing any function. If no

phenotypical characteristics can be related to the patented DNA sequence in a commercial plant variety, the function of the patented DNA sequence is not expressed (in the words of Article 9 of the Directive it is not performing its function) and thus patent protection on the originally patented DNA sequence should not in these expert's view extend to the variety.

This expert is of the opinion that the words "performs its function" in Article 9 have been correctly interpreted by the CJEU in the case at issue and fully agrees with the considerations of the Court outlined in item 40 of the decision.

Other examples can also be conceived. A fruit with a patented gene could be processed into fruit jam, and the question then arises whether the producer of the jam infringes the patent for the fruit gene present in the fruit jam. Another example is a blood product produced from blood which contains patented genetic information. Would there be an infringement by the producer of such blood products?

However, in both of these cases the Court would also have to consider and ascribe some meaning to the term "isolated" or "purified" that would be in such a claim in order to render the patent claim to a gene novel over the gene in nature. This was indeed done by first instance Court in the United Kingdom where the Judge held that the DNA in the soya meal was not "isolated" within the meaning of the claim and denied infringement of the patent.¹⁹⁹

In conclusion, the majority of the (11/15) Experts are of the opinion that the interpretation of the phrase "performs its function" in Article 9 provided by the Court may cause practical enforcement problems with regard to certain commercialization practices if this interpretation were to be generally extended to all claims directed to nucleic acids encoding genes isolated from human and animals per se.

5.5 Answer of the CJEU to Question 2

The Court answered Question 2 as follows:

2. Article 9 of the Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes the national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it.

5.5.1 Majority Opinions

The majority of the (11/15) Experts are of the opinion that this answer is the most controversial point of the decision with regard to the intentions of the Directive as laid down in the Recitals and the relationship between of Article 5(2) and Article 9 of the Directive and the pre-existing patent laws in the majority of the contracting states which do not preclude absolute product protection in general (see Annex 1).

¹⁹⁹ Monsanto v Cargill [2007] EWHC 2257 (Pat).

The first striking aspect of the answer to Question 2 is the fact that the Court concludes that Article 9 precludes national patent legislation from “offering absolute protection” to the patented product, i.e. for a nucleic acid molecule. However, it seems clear from the form and content of the Directive that considerations as to what should be considered patentable, on the one hand, and what the scope of protection is, on the other hand, are separate issues that are treated in two distinct chapters of the Directive entitled the “Chapter I Patentability” and “Chapter II Scope of Protection”. The Court seems to have found this distinction to be of little importance. Article 9 relates to the scope of protection, whereas Articles 3 and 5 determine the subject matter that is eligible for patentability.

Hence, the derivation of a prevention of absolute product protection for nucleic acid molecules accentuating Article 9 without giving full consideration to Article 3 and 5 of the Directive may not be in line with the intention of the Directive.

The answer provided by the Court when addressing Question 2 seems to have its root in the logic used by the Court in addressing Question 1. In its analysis of Question 1 and Article 9 of the Directive, the Court repeatedly referred to the material in which the DNA was found (see for example, item 34: “genetic information contained in the patented product or constituting that product ‘performs’ its function in the ‘material ... in which’ that information is contained”; item 35: “in the actual material in which the DNA sequence containing the genetic information is found”; item 36: “the biological material in which it is incorporated”; item 38: “perform the function it performed in the initial material from which the material in question is derived”; item 46: “the patented DNA sequence performs its function in the material in which it is incorporated”; etc.

This logical connection between the nucleic acid molecule “performing its function” in the “material in which it is found” is understandable when considering the fact that Article 9 extends “the protection conferred by a patent on a product containing or consisting of genetic information ... **to all material ... in which the product is incorporated and in which the genetic information is contained and performs its function**”.

However, the Court then provided several interesting remarks in addressing Question 1 with regard to the ability of a nucleic acid molecule (DNA) to perform its function and patent protection for a nucleic acid molecule **as such**, i.e. uncoupled from “the material in which it is incorporated”. For example items 43 and 44 of the decision state:

43. In that regard, it should be borne in mind that recital 23 in the preamble to the Directive states that ‘a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention’.

The Court continued in item 44 with:

44. Moreover, the import of recitals 22 and 24 in the preamble to, and Article 5(3) of the Directive is that a DNA sequence does not enjoy any protection under patent law when the function performed by that sequence is not specified.

These statements seem to be borne from the concept in Recitals 22-24 that a mere DNA sequence, for example an EST (“Expressed Sequence Tag” which is a randomly sequenced piece of cDNA having no known function) is not patentable.

However, these statements do not mention the fact that Recital 22 and Article 5(3) explicitly state that “the industrial application of a sequence or a partial sequence of a gene must be disclosed **in the patent application (as filed)**”. Recital 22 does not require that an industrial application (or the function) be incorporated into the claims. Likewise, Article 5(3) does not require that an industrial application (or the function) be incorporated into the claims.

Moreover, this analysis does not address the fact that the explicit wording of Article 5(2) which states that an isolated element from the human body such as a sequence or partial sequence of a gene may constitute a patentable invention, even if the structure is identical to that of a natural element. Article 5(2) of the Directive does not make the patentability of a sequence or partial sequence of a human gene conditional upon the function of the human gene being incorporated **into the claim**. This should apply by analogy to plant genes as well. Moreover, while the above-mentioned recitals may provide an indication as to what was intended by the Directive, it is Article 5 which clearly does not prescribe “purpose-bound” or “functionally limited” language to be incorporated into a claim.

Finally, according to all of Experts, there is nothing in Article 3 of the Directive that would indicate that any biological material that is isolated from its natural environment, even if it previously occurred in nature, should be limited “purpose-bound” or “functionally limited” language to be incorporated into a claim.

Many (11/15) Experts were of the opinion that Recital 23, which reads

(23) Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;

Does not specify that the function of a DNA sequence must be written into the patent claim, but rather, merely requires that the patent specification indicate what the function of a particular DNA sequence is. Many of the (11/15) Experts thought that Recital 23 encompasses a situation concerning ESTs (expressed Sequence Tags, see above), where a random DNA sequence cloned from a cDNA library is described in a patent specification without providing any function of the sequence. This would be in line the fact that the directly antecedent Recital 24 deals exactly with such a situation.

Moreover, (11/15) Experts do not see a discrepancy between Recital 23 and Article 3(2) of the Directive because this article explicitly states that “biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention, i.e. may be the subject matter of a claim, without any functional limitation in the claim as long as the function is provided or indicated in the patent specification. This would also seem to conform to Recital 15 of the Directive which states that “no prohibition or exclusion exists in national or European patent law (Munich Convention) which precludes *a priori* the patentability of biological material”.

While the majority (11/15) of Experts are of the opinion that none of Recitals 22 to 24 or Articles 3 and 5(2)(3) of the Directive prohibit the absolute product protection of a nucleic acid sequence as such, the Court nevertheless stated in item 45:

45. Since the Directive thus makes the patentability of a DNA sequence subject to indication of the function it performs, it must be regarded as not according any protection to a patented DNA sequence which is not **able** to perform the specific function for which it was patented.

For the first time in its analysis, the Court discusses the protection for a patented DNA which is not **able** to perform its function, as opposed to “performs its function”.

The majority (11/15) of Experts are of the opinion that this remark by the Court seems to decouple the concept of “performs its function” in “the material in which it is incorporated” in Article 9 of the Directive and creates a relationship between the patentability of a DNA sequence **as such** (“any protection to a patented DNA sequence” and the **ability** of the DNA to perform its function whether it is in incorporated into a biological material (as required by Article 9) or not.

This viewpoint is critical to the analysis by the Court because there is a significant difference as to whether a DNA “performs its function in the material in which it is incorporated” or is “**able** to perform its function”. For example, while the dried DNA fragment referred to in example above does not and cannot perform any function in its dry state, it is “able” or “capable” of performing its function when placed in the proper environment.

The Court seems to have recognized the distinction between “performs its function” and “able to perform its function” in item 45 of the decision. Nevertheless, in addressing Question 2, the Court applied Article 9 of the Directive to a DNA molecule as such which is not in a material in which it can perform its function.

It seems that at this point the Court started to intertwine the concept of absolute product protection as afforded to nucleic acid sequences by the patent statutes of the various European countries and Article 5(2) of the Directive with the concept of **extending** patent protection to biological material incorporating nucleic acid sequences as regulated by Article 9 of the Directive.

This can also be seen from item 49 of the decision:

49. Such a sequence does not, therefore, enjoy patent right protection, since neither Article 9 of the Directive nor any other provision thereof accords protection to a patented DNA sequence which is not able to perform its function.

Once the Court established this artificial connection between Articles 5(2) and 9 of the Directive, it came to the conclusion expressed when answering Question 2:

62. Accordingly, in so far as the Directive does not accord protection to a patented DNA sequence which is not **able** to perform its function, the provision interpreted precludes the national legislature from granting absolute protection to a patented DNA sequence **as such**, regardless of whether it performs its function in the material containing it.

Most Experts (11/15) are of the opinion this conclusion misinterprets the Biotech Directive because the Directive does not “preclude the national legislature from granting absolute protection to a patented DNA sequence as such”.

In addressing Question 2, the Court examined Recitals 3, 5-7, 8 and 13 in items 53-56 of the decision and discussed the differences and potential differences in National Law and the disadvantages to the EU based on these differences. The Court then underscored the importance of harmonizing community legislation in items 56-59.

However, the Court did not seem to address one very important fact in its analysis in item 58. Here the Court stated that Article 9 of the Directive was intended to “ensure the same protection for patents in all Member States”. While this is true, several important aspects should also be taken into account.

First, Article 9 of the Directive explicitly states that “the protection conferred by a patent on a product containing or consisting of genetic information shall **extend** to all material...”. Article 9 was intended to provide patent protection not only for the original biological material but also to extend patent protection to the progeny of the original biological material. This was to take into account the fact that unlike typical physical substances and objects, biological material is self-replicating and the progeny of such biological material must enjoy patent protection as well. Thus, Article 9 seems to be formulated such that product protection is explicitly extended beyond that of the “normal” absolute product protection afforded by the various national patent laws. This interpretation is in line with Recital 8 of the Directive that states that the “legal protection of biotechnological inventions **does not necessitate** the **creation** of a **separate** body of law **in place** of the rules of national patent law”. It is also in line with Recital 46 of the Directive which states:

(46) Whereas, in view of the fact that the function of a patent is to reward the inventor for his creative efforts by granting an exclusive but time-bound right, and thereby encourage inventive activities, the holder of the patent should be entitled to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the use of patented, non-self-reproducing products, that is to say the production of the patented product itself.

Second, the protection conferred by Article 9 of the Directive “shall extend to all **material ... in which the product is incorporated** and in which the genetic information is contained and performs its function.

Hence, Article 9 does not “restrict” protection, but rather extends it, and Article 9 extends protection to material in which a nucleic acid is incorporated, but does not regulate or legislate the situation where the nucleic acid as such is the subject matter of a patent claim, i.e. the case where a nucleic acid molecule is not incorporated into biological material.

Third, Article 3 of the Directive clearly states that:

Article 3

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

The purpose of the Directive is to provide (“extend”) patent protection for biotechnology inventions, in particular self-replicating living organisms. The Directive is concerned with the concept of “patent exhaustion” – the effective relinquishment of patent rights after the commercial sale of a patented product. The Directive was meant to provide for a patent right that would not be exhausted if a commercial product was the progeny that resulted from replication of an original patented product.

This does not seem to have been adequately considered by the Court.

Moreover, there seems to be a discrepancy between the intention of the Directive in Recitals 8 and 13 and the conclusions drawn by the Court.

The Court recognized these intentions in item 54 of the decision:

54. Recitals 8 and 13 in the preamble to the Directive further state that:

- legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law;
- the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions given that they must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfil the requirements for patentability;
- the Community’s legal framework for the protection of biotechnological inventions can be limited to laying down certain principles as they apply, inter alia, to the patentability of biological material as such and to the scope of protection conferred by a patent on a biotechnological invention.

Moreover, in item 56 of the decision, the Court expressly stated that the Directive was “intended to effect a harmonization which was **limited** in its substantive scope”.

Nevertheless, the conclusions of the Court in item 62 on the preclusion of the national legislature from granting absolute protection to a patented DNA sequence as such seems to be at odds with this “limited” intention of the Directive in light of the national patent laws which existed prior to the implementation of the Directive and which were considered by most to provide for absolute protection for products for chemical substances such as nucleic acid molecules.

Finally, the Court did not address the intentions of Recitals 1-3 of the Directive:

- (1) Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions will certainly be of fundamental importance for the Community's industrial development;
- (2) Whereas, in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;

(3) Whereas effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology.

It could be argued in this regard, however, that the CJEU has aimed at providing harmonisation by holding that absolute product protection for DNA sequences is no longer allowed. That could be seen in the context of Recital 3 of the Preamble.

Whether the solution provided by the CJEU leads to effective protection is indeed a question which has been discussed in detail. The majority (11/15) of the Expert Group considers the legal reasoning behind the judgement to be at times quite difficult to follow and believes the court has unnecessarily intertwined patentability with scope of protection issues. With a judgement based on such uncertain legal reasoning, it can be doubted whether the solution provided constitutes effective protection.

5.5.2 Minority Opinions

A minority (4/15) of the Experts expressed the opinion that the conclusion of the Court is correct because it simply confirms the implicit removal of genomic nucleic acid sequences from the scope of protection of a patent that was intended from the inception of the Directive.

These same Experts are of the opinion that absolute product protection for nucleic acid molecules overly rewards patent applicants for their contribution to the public (the arguments for this are further developed in section 5.8.3 of this Report). Patent law must give enough incentives to reward other patent applicants that have discovered another novel function and industrial application of a given nucleic acid. Other rationale given in the discussion about absolute or purpose-restricted protection were the assumption that isolation and determination of a nucleotide sequence of a particular gene per se is a discovery of that which already exists in nature and thus cannot be considered an invention (the arguments for this are also further developed in section 5.8.3 of this Report).

With regard to the Court's interpretation of Recitals 22-24 in connection with Article 5 and 9 of the Directive, some (4/15) Experts considered that Recital 23 should be interpreted as indicating that the scope of protection of a claim should be limited by a function because Recital 23 states that "a mere DNA sequence without indication of a function does not contain any technical teaching and is therefore not a patentable invention". Such an interpretation was regarded as especially important for nucleic acid-related inventions since Articles 5 and 9 of the Directive make a specific reference to the function of genetic material in regard to patentability and scope of protection, respectively. A minority (4/15) of Experts expressed the opinion that this conclusion is correct and in line with Recital 23 which makes clear that Article 5 and Article 9 of the Directive have to be seen in a joint legal context that gives special attention to inventions based on genomic DNA.

According to these Experts the Directive does not encourage absolute product protection for DNA and clearly differentiates inventions based on genomic DNA from other technical areas where absolute product protection is provided.

A minority (4/15) of the Experts are of the opinion that the decision of the CJEU is correct in its interpretation of the wording and the intention of Directive 98/44/EC because, by explicitly mentioning DNA sequences as biological components, the EU Directive shows that specific rules and

regulations concerning gene sequences are necessary in comparison to other material. One reason for this lies in the function of DNA: While it is true that DNA can be described as relatively simple biochemical substance, its biological functions are not reduced to the characteristics of its chemical components. Rather, DNA has to be regarded as a code of information that reveals its function in a much more complex way. In the view of these Experts, the Commission should render a legal clarification to make sure that the decision of the CJEU and the national laws in France, Germany, Luxembourg, Poland and Italy as well as the resolutions of the EU parliament are correct in the interpretation of Directive 98/44/EC and that other countries should seek to bring their decision making in line with this interpretation. The Commission should encourage the EPO to do the same. Furthermore, the Commission should also clarify that no absolute product protection can be given if inventions overlap with the exclusions of Article 4: If the scope of an inventions overlaps with what is excluded from patentability such as plant and animal varieties or usage of essentially biological processes for breeding (or the products derived), the scope of the patent has to be limited to avoid any overlap.

5.6 Answer of the CJEU to Question 3

The Court answered Question 3 as follows:

3. Article 9 of the Directive precludes the holder of a patent issued prior to the adoption of that directive from relying on the absolute protection for the patented product accorded to it under the national legislation then applicable.

In this context, the Court stated in item 65 that:

65 Like the second question, the third is based on the premise that a national provision such as Article 53 of the 1995 Law did in fact accord absolute protection to the patented product when the patent was issued prior to the Directive.

With regard to the second question the Court stated in item 52 that:

52. That question is based on the premise, referred to in the order for reference, that a national provision such as Article 53 of the 1995 Law does in fact accord absolute protection to the patented product.

It is interesting to note that the Court describes absolute product protection as a “premise”, i.e. something assumed to be true, but offers no explanation as to why this “premise” is not true.

A minority (3/15) of Experts are of the opinion that the CJEU correctly assumes that the Directive in this regard is self-explaining and therefore no further justification has to be presented.

5.7 Answer of the CJEU to Question 4

The CJEU answered the 4th question as follows:

4. Articles 27 and 30 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, constituting Annex 1C to the Agreement establishing the World Trade Organisation (WTO), signed at Marrakesh on 15 April 1994 and approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) do not affect the interpretation given of Article 9 of the Directive.

In its decision the Court stated:

76 On the assumption that ‘exceptions to rights conferred’ could be regarded as encompassing not only exclusions of rights but also limitations on those rights, it should be pointed out that an interpretation of Article 9 of the Directive limiting the protection it confers to situations in which the patented product performs its function does not appear to conflict unreasonably with a normal exploitation of the patent and does not ‘unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties’, within the meaning of Article 30 of the TRIPS Agreement.

All Experts agree that the Court is correct in assuming that it would not be “unreasonable” to limit the protection of a claim to a nucleic acid in situations similar to the specific circumstances of the Monsanto case. However, most (11/15) Experts also agree that there are ample examples in which it would be completely unreasonable to limit protection of a claim directed to a nucleic acid to only those situations where the nucleic acid actually performs its function. Some (4/15) of the Experts are of the opinion that function limited patent protection should be generally applied in the field of nucleic acids related inventions.

5.8 Nature and Applicability of C-428/08

C-428/08 initiated a wave of commentary from interested parties shortly after its publication in 2010. In the one direction, many interested parties expressed a deep-seated concern that this decision would have far-reaching negative implications and effects on the enforcement of patent applications/patents containing claims to nucleic acid molecules and biological material comprising nucleic acid molecules. In the other direction, a wave of relief was propagated by several parties averse to allowing absolute patent protection for hereditary material. In the interim period between 2010 and the present, the initial concerns and relief have subsided somewhat, but the interested parties are nevertheless left with assessing the practical implications of the decision.

The following deals with some of the more important considerations in this respect.

5.8.1 Should the reasoning of the CJEU be confined to the specific facts of the case and why (not)?

The majority of (11/15) Experts are of the opinion that the reasoning in C-428/08 should be confined to situations similar to the specific facts of the case.

This is because:

- the DNA encoding the bacterial EPSPS enzyme that was found to be present in the soy meal was never intended to perform the function of acting as a template for the production of the protein

since this function had already been accomplished in the soy plants themselves before the meal was produced;

- the nature of the biological material as “dead material” (see item 48 of the decision); and
- the fact that Monsanto patent under consideration did not have claims to soy meal comprising the EPSPS gene as such or products derived from live soy plants comprising the EPSPS gene.

Moreover the answer to Question 1 that the CJEU provided was very specifically directed to the circumstances of the case.

A minority (3/15) Experts are of the following opinion: While it is true that the decision of the CJEU should be interpreted in its context, the decision has a more general implication. Taken together, the decision of the CJEU and the national laws in France, Germany, Luxembourg, Poland and Italy are outlining a correct in the interpretation of Directive 98/44, taking into account the intention of the legislator as expressed by the resolutions of the EU Parliament. Therefore, other countries should seek to bring their decision making in line with this interpretation and the Commission should seek measures to harmonise EU patent law to that extent. The Commission should also encourage the EPO to align its granting practises with the said interpretation.

5.8.2 Has the Monsanto decision effectively introduced purpose or function-limited protection for DNA, and why (not)?

In order to address this question, it is interesting to examine judgements of other high courts in the EU that have related to the scope of protection of claims to a nucleic acid encoding a human or animal gene sequence that did not provide a function of the sequence in the claim.

On such decision is the well-publicised judgement “Human Genome Sciences vs. Eli Lilly” of the Supreme Court of the United Kingdom ([2011] UKSC 51) handed down on 2 November 2011. In this decision, which was taken well after the decision of the CJEU in C-428/08 was given on 6 July 2010, the members of the Court considered a main claim to an isolated nucleic acid molecule that encompassed a human gene but did not provide a function of the sequence in the claim:

1. An isolated nucleic acid molecule comprising a polynucleotide sequence encoding a Neutrokin- α polypeptide wherein said polynucleotide sequence is selected from the group consisting of:
 - (a) a polynucleotide sequence encoding the full length Neutrokin- α polypeptide having the amino acid sequence of residues 1 to 285 of SEQ ID NO: 2; and
 - (b) a polynucleotide sequence encoding the extracellular domain of the Neutrokin- α polypeptide having the amino acid sequence of residues 73 to 285 of SEQ ID NO:2.

While the Supreme Court provided a detailed analysis of a number of decisions from the Technical Board of the EPO including T604/04; T870/04; T1329/04; T898/05; T1165/06; T1452/06; and T18/09, which all relate to some extent to claims directed to nucleic acids and the disclosure in a patent document on the function (industrial applicability) of said nucleic acids, the Court did not mention the CJEU decision at all.

Furthermore, while the European Patent Office implemented portions of the Biotech Directive into Rules 26-29 EPC 2000 without being required to do so, mentions the Directive in section G.II.5.2/5.3 of the Guidelines for Examination, and has considered decisions of the CJEU on biotechnology issues in past decisions of the Technical Boards (see T2221/10, items 37-39, and T1441/13, item 4.1, which discuss the CJEU decision CD-34/10 relating to the patentability of human embryos and stem cells), we are not aware of an EPO decision which cites CJEU decision C-428/04 to indicate that the wording of a claim to a nucleic acid sequence should be limited by incorporating the function of the nucleic acid into the claim. Moreover, the EPO continues to grant claims on nucleic acid molecules per se, i.e. without requiring a function to be expressly stated in the claims, provided that the respective application plausibly discloses a function and thus meets the requirements of patentability, and in particular industrial application. It should be noted that whether or not a function is explicitly set out in a patent claim will make no difference to its scope of protection, which will be determined by the courts. Under current practice, a claim to a nucleic acid will be considered to cover all uses and functions of the nucleic acid, or of the protein encoded by it.

Recently, the Federal Court of Justice of Germany dealt with a case relating to a national patent stemming from European Patent EP 959 132 with the following claim 1:

1. A nucleic acid molecule of a tandem duplication mutant encoding FMS-like tyrosine kinase 3 (FLT3) and has a nucleotide sequence with either:
 - a) a tandem duplication mutation in the amino acid sequence of the juxtamembrane of FLT,
or
 - b) a tandem duplication mutation in the nucleotide sequence of exon 11 or exons 11 to 12 of FLT3 without a shift in the reading frame.

Hence, the Court had to assess the patentability of a nucleic acid claim that was not purpose-limited.

The nucleic acid was described in the original application as being useful for the diagnosis of leukemia in human patients. Further claims included methods for the detection of the above nucleic acid as well as the use of the nucleic acid in diagnosis and for the preparation of a medicament.

The plaintiff asserted that the subject matter of the above claim was a non-patentable discovery. However, the Court held:

49 c) The objection that the subject matter of claims 1 and 2 are an unpatentable discovery is also unsubstantiated.

50 aa) A discovery as well as a scientific theory or a mathematical method is not capable of being patented as such according to Article 52(2)a EPC. However, in contrast to the decision of the Supreme Court of the United States (566 U.S. [2012] - Mayo v. Prometheus) a teaching of technical activity that teaches the use of a discovery to bring about a certain result is, according to European – and German – law capable of being patented irrespective of whether the teaching contains an “inventive surplus” the extends beyond the use of the disclosed connection to natural law

51 bb) Hence, there is no bar to patentability of the subject matter of claims 1 and 2 just because the technical teaching is exhausted in the instruction to provide the nucleic acid molecule indicated in these claims. Nothing else can be derived from Rule 29 Implementing Regulations to the EPC, which in agreement with Sec. 1a I German Patent Act, dictates that the human body at the various stages of its formation and development as well as the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute a patentable invention. This only reinforces the principle already stemming from the concept of an invention that, not the discovery of a sequence, but rather the disclosure that and how it can be made technically useful through isolation is what makes a technical teaching patentable (Rule 29 2 Implementing Regulations to the EPC, Sec. 1a II German Patent Act). The “recognizable characterization” of the sequence as isolated or obtained by a technical process that is thought to be necessary by the plaintiff is not required, however, because it is intrinsic to every product claim that it characterizes the technical teaching under protection through the indication of the product, i.e. that this product is made available (through a technical process).

52 cc) The objection – which was not presented in detail – that the invention was allegedly filed “unfinished” and that undue burden was allegedly necessary to subsequently verify the technical teaching is not decisive either. The inventor neither has to recognize why the technical teaching of the invention functions nor does he have to provide a scientific explanation. It suffices that he hands over to the skilled person that which is necessary for him to practice the invention. [...]

The Federal Court of Justice of Germany did not mention C-428/04 in its analysis or its reasons for the decision, even though the Court had to decide on the patentability of claim 1 which was not purpose-limited well after the publication of C-428/04.

Based on the above, the majority (11/15) of the Experts do not believe that the CJEU decision C-428/04 has resulted in a general restriction in claim language with regard to the grant of European patents relating to nucleic acids encoding human or animal genes or in the scope of protection of claims directed to nucleic acid molecules as such.

The minority (4/15) of the Experts is of the opinion that the CJEU decision C-428/04 has resulted in a general restriction in functional- or purpose-limited patent scope with regard to the grant of European patents relating to nucleic acids encoding human or animal genes or in the scope of protection of claims directed to nucleic acid molecules as such. The above cited decision of the German Court only related to the question whether a nucleic acid molecule as such is exempted from patentability because it is to be considered a discovery. Thus, the Court did not decide on patent scope, that is how narrow or broad the nucleic acid is to be protected.

One expert agrees that the answer of the CJEU to question 2 in case C-428/08 has been somewhat awkwardly formulated. This expert is of the view that with its decision the Court intended to clarify the meaning of Article 9 where it refers to “performs its function” and its link to recital 23. This expert is of the opinion that while it is not required that the claims contain a function, Recital 23 however means that in case a function cannot be identified from the patent application as a whole, the claimed invention cannot be granted patent protection.

A minority (3/15) of Experts are of the following opinion: It is surprising that so far the decision of the CJEU is disregarded by national courts. In the view of these Experts, the Commission should clarify that the decision of the CJEU and the national laws in France, Germany, Luxembourg and Italy as well as the resolutions of the European Parliament are correct in their interpretation of Directive 98/44/EC and should encourage that other Member States, national courts, the future Unified Patent Court to bring their decision-making in line with this interpretation. The Commission should also encourage the EPO to align its granting practises with the said interpretation.

5.8.3 Is there a convincing rationale for introducing purpose or function limited product protection for DNA sequences, and if so which consequences might such introduction have for past and present patent filing and patent enforcement?

A wide range of issues have been discussed in the Group regarding the question as to whether there is a good rationale or not for introducing function or purpose limited product protection for DNA sequences. In view of time constraints rather suddenly imposed by the Commission related to the end of the mandate of the Expert Group, no consensus could be found within the Group as to whether the issues had been discussed to a satisfactory level of detail to arrive at a common ground to add those discussions in the main body of this Report.

Even though all Experts agreed that time pressure has indeed affected the level of detail within which issues relating to this subject were discussed, a majority (11/15) of Expert Group members is nevertheless of the opinion that most if not all of the matters raised were already commonly known for some years²⁰⁰. These considerations include scope of protection versus contribution to the public; special nature of genomic nucleic acids as carriers of genetic information; the possibility to “work around” a patent claim on genomic DNA; the dependency of third parties on original patent to a gene and encouragement/discouragement to research; legal certainty for third parties; and the purpose and transposition of the Directive.

All Experts agreed that these issues merit discussion and that the public is entitled to know the views of the Experts on these matters. However, in view of the majority (11/15) of Experts a Report without any discussion of the issues relating to the above question would be entirely unsatisfactory.

It is therefore that the majority (11/15) of Experts have wanted the discussion of those issues added in the Report. The majority has provided their opinion, which they consider to be an overview of commonly known arguments relating to the question as to whether there is a convincing rationale for introducing function or purpose limited protection for DNA sequences in Annex 5 to this Report.

A minority (4/15) of the Experts were of the opinion that there had not been an agreeably detailed discussion of the above-mentioned matters so that it could be added in the main body of the Report. As there was no common ground as to which issues and which discussion to add about these issues in the main body of the Report, this minority has provided their comments relating to the issue as to whether there is convincing rationale for introducing function or purpose limited protection for DNA sequences in a separate document in Annex 6.

²⁰⁰ see, Bostyn, S.J.R., Patenting DNA Sequences (Polynucleotides) and Scope of Protection in the European Union: An Evaluation, Luxembourg, European Communities 2004,56-65, upon which the present overview is largely inspired.

6 Conclusions and Recommendations

None of the Experts recommends amending the Biotech Directive. However, one Expert is of the opinion that, if clarification as recommended in the minority opinion cannot be achieved, then the Directive should be amended to the extent expressed in the minority opinion.

6.1 Conclusions and Recommendations of the Majority of the Experts

The majority (11/15) of the Experts consider that the Directive codifies a unified text that has been transposed in a harmonised manner by the vast majority of the Member States. No action need be taken pursuant to the fact that five Member States transposed the Directive with different texts and consequences.

After intense and detailed discussion, these Experts are of the opinion that the CJEU was correct in coming to the conclusion that, in a situation such as C-428/08 (“Monsanto”) case where an (intact) genomic DNA sequence encoding for a gene was present as an artefact in biological material, the presence of such DNA is not an infringement of the patent because the DNA does not perform its function in that material within the meaning of Article 9 of the Directive.

However, these Experts also believe that decision C-428/08 should not be interpreted as limiting absolute product protection typically afforded to chemical substances for genomic nucleic acids such that the function of the genomic nucleic acid sequence had to be incorporated into the language of the patent claim. While the vast majority of the Experts agree that while one or more functions that fulfils the requirements of patentability, in particular industrial applicability, sufficiency of disclosure and inventive step, must be indicated in the patent description in accordance with Article 5(3) and Recital 23, these Experts are of the opinion that the scope of protection of the claims of the patent should not be restricted to that function.

These Experts are of the opinion that limiting the scope of protection of genomic nucleic acid claims per se to one or more particular functions disclosed in the description would not have any substantial impact on the utilization of patents disclosing this subject matter.

Given the intention of Recitals 1 to 3 of the Directive with regard to the “importance for the Community’s industrial development”, the nature of the “high-risk investment” in the biotechnology filed and “to maintain and encourage investment in the field of biotechnology”, these Experts are of the opinion that conventional absolute product protection for genomic nucleic acids for the limited 20 year lifetime of a patent is commensurate with the inventors contribution to the public.

These same conclusions should be applied to genomic nucleic acids, regardless of their origin.

6.2 Conclusions and Recommendations of the Minority of the Experts

The minority (4/15) of the Experts are of the opinion that in their national implementation of Directive 98/44/EC, Germany, Italy, France and Luxembourg passed amendments in legal texts to

specify and clarify the articles of said Directive. Despite of the differences in the wording of these amendments, their common purpose is the reduction of scope of DNA sequences and other nucleic acid-related inventions to their function or purpose described in the patent, in order to avoid too many patent dependencies, and to strike the right balance.

The conclusions of the CJEU in *Monsanto C 428-08* are correct²⁰¹. The CJEU decision in *Monsanto C-428/08* has provided a general, authoritative, clarifying statement for the interpretation of Directive 98/44/EC, which confirms that protection for DNA sequences should be limited to the purpose or function of the novel nucleic acid. The conclusion is correct in precluding the national patent legislation from offering absolute protection to the patented product as such. Thus, the CJEU rejected the absolute product protection doctrine for nucleic acid-related inventions. Moreover, the CJEU also confirmed that the DNA has to perform its function in the material containing it to fall under the scope of the patent.

Based on the facts of the case, the Experts agree that both the reasoning by the Court and its wider application to DNA-related inventions is correct. Moreover, the decision of the CJEU is completely in line with the interpretation of the Directive in national laws in France, Germany, Luxembourg, Poland and Italy, as well as the resolutions of the European Parliament.

The CJEU in its *Monsanto* ruling has confirmed that functional restriction of the absolute scope of protection of patents on DNA related inventions is in compliance with Directive 98/44/EC and the TRIPs Agreement²⁰². The effect of the CJEU's *Monsanto* ruling is the exhaustive harmonisation of EU law and the implementation of a function-bound restriction of patent scope on DNA related inventions as a general rule.

The Commission should clarify that the decision of the CJEU and the national laws of France, Germany, Luxembourg and Italy, as well as the Resolutions of the European Parliament are correct in their interpretation of Directive 98/44/EC and should encourage that other Member States, national courts, the future Unified Patent Court to bring their decision-making in line with this interpretation. The Commission should also encourage the EPO to align its granting practices with the said interpretation.

²⁰¹ "2. Article 9 of the Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes the national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it."

²⁰² The CJEU in *Monsanto* answered the 4th question as follows: "4. Articles 27 and 30 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, constituting Annex 1C to the Agreement establishing the World Trade Organisation (WTO), signed at Marrakesh on 15 April 1994 and approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) do not affect the interpretation given of Article 9 of the Directive". In its decision the Court also stated in #76 "On the assumption that 'exceptions to rights conferred' could be regarded as encompassing not only exclusions of rights but also limitations on those rights, it should be pointed out that an interpretation of Article 9 of the Directive limiting the protection it confers to situations in which the patented product performs its function does not appear to conflict unreasonably with a normal exploitation of the patent and does not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties', within the meaning of Article 30 of the TRIPS Agreement."

Furthermore, the Commission should also clarify that no absolute product protection can be given if inventions overlap with the exclusions of Article 4²⁰³. If the scope of an invention overlaps with what is excluded from patentability such as plant and animal varieties or usage of essentially biological processes for the production of plant and animals (or the products derived thereof), the scope of the patent has to be limited to avoid any overlap.

²⁰³ "Article 4: 1. The following shall not be patentable: (a) plant and animal varieties; (b) essentially biological processes for the production of plants or animals." (Directive 98/44/EC).

Enclosures to the subreport C:

Annex C1: Overview National Laws on Nucleic Acid Sequences

Institut der beim Europäischen Patentamt zugelassenen Vertreter
Institute of Professional Representatives before the European Patent Office
Institut des mandataires agréés près l'Office européen des brevets

Ausschuss für Biotechnologische Erfindungen
Committee on Biotechnological Inventions
Commission pour les Inventions en Biotechnologie

22 April 2016

Overview National Laws on Nucleic Acid Sequences

The table below contains answers to the following questions:

- 1) Is there purpose/function limited protection of nucleic acid sequences in the patent legislation of your jurisdiction? (YES/NO)
- 2) Could you please explain this and cite the relevant legal provision(s)?²⁰⁴
- 3) Has the patent office in your jurisdiction published guidelines for examination of purpose/function limited protection of nucleic acid sequences? If yes, could you please cite the relevant part(s) of those guidelines?

²⁰⁴ Please note that the English translations provided are not necessarily official.

	1	2	3
AL	NO	<p>The industrial applicability of gene sequences must be mentioned in the application in order to meet the requirement of industrial applicability.</p> <p>Excerpts from ALBANIAN LAW Nr. 9947 dated 07.07.2008 ON INDUSTRIAL PROPERTY:</p> <p>Article 5 Patentable Inventions [...] 5. Biotechnological inventions shall also be patentable if they concern: [...] ç) an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.</p> <p>Article 6 Exceptions to patentability Patents shall not be granted in respect of: [...] 3. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene. [...]</p> <p>Article 10 Applicability in Industry and Agriculture [...] 2. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.</p>	NO

AT	NO	<p>A purpose/function has only to be indicated in the specification and not in the claims. It is needed to meet the requirement of industrial applicability and does not limit the scope of the claims (see Sec 1 and 89a of the Austrian Patents Act).</p> <p>Excerpts from the Austrian Patents Act:</p> <p>§ 1. Patentable inventions (1) On request, patents shall be granted for inventions in all fields of technology, provided that they are new (section 3), not obvious to the person skilled in the art from the state of the art, and susceptible of industrial application. (2) Inventions that fulfill the conditions of subsection 1 shall be patented, even if they concern a product consisting of or containing biological material or a method by means of which biological material is produced, processed or used, wherein biological material means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system. These patentable inventions shall also include 1. biological material which is isolated from its natural environment or produced by means of a technical method even if it previously occurred in nature; 2. an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element. [...] (3) The following in particular shall not be regarded as inventions: [...] 2. the human body at the various stages of its formation and development; 3. the simple discovery of one of the elements of the human body, including the sequence or partial sequence of a gene; [...]</p> <p>§ 89a.</p>	<p>No, but there exist examination guidelines in which the industrial applicability of sequences is discussed (the most relevant parts thereof are cited below).</p> <p>Excerpt from the Examination Guidelines of Biotechnological Inventions of the Austrian Patent Office:</p> <p>6 Industrial Applicability The Patent Act (§ 1 para. 1 of the Patent Law) stipulates that an invention must be industrially applicable. This is not the case if the product is unusable or useless. It is therefore necessary to consider whether the claimed invention fulfills a useful purpose. Directive 98/44/EC (recital 22) and § 89a Patent Law stipulate that the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed. Therefore, the intended use of a sequence, i.e. its function, has to be derivable from the application as filed at the filing date. [...] The possible use of short DNA sequences or ESTs (= partially sequenced cDNA clones) as probes, is not considered to be sufficient. [...]</p>
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		The industrial application of a sequence or partial sequence of a gene must be disclosed in the application.	
BE	NO	<p>The industrial applicability of gene sequences must be mentioned in the application in order to meet the requirement of industrial applicability.</p> <p>Excerpts from the Belgian Code of Economic Law:</p> <p>Art. XI.5. [...]</p> <p>§ 6. The human body, at the various stages of its formation and development, and the simple discovery of one of parts thereof, including the sequence or partial sequence of a gene, are not patentable.</p> <p>A portion of the human body which has been isolated, or otherwise produced by a technical method, including a sequence or a partial sequence of a gene, is susceptible to patenting, even if the structure of that part is identical to that of a natural element.</p> <p>The industrial application of a sequence or a partial sequence of a gene which serves as a basis for the invention is to be concretely disclosed in the patent application. [...]</p>	NO
BG	NO	According to Art. 37 (5) of the Bulgarian Patent Law (last amendment 18.05.2012), a purpose/function has only to be indicated in the specification and not in the claims. It is needed to meet the requirement of industrial applicability and does not limit the scope of the claims.	Art. 36(6) of the Guideline for examination (19.03.2008) indicates only the case when a deficiency of nucleic acid sequences have been noticed and the time given to the Applicant to correct them.
CH	NO	<p>Excerpts from the Federal Act on Patents for Inventions (Patent Act)(text available under https://www.admin.ch/opc/en/classified-compilation/19540108/index.html):</p> <p>Art. 1b 1 A naturally occurring sequence or partial sequence of a gene is not patentable as such. 2 Sequences that are derived from a naturally occurring</p>	<p>Extract from CH - Examination Guidelines:</p> <p>11.2.2 Naturally occurring DNA sequences; sequences derived therefrom</p> <p>Claims on sequences or partial sequences of naturally occurring genes both in their natural environment as well as in isolated form (as genomic DNA) are not permissible. It should be noted that Art. 1b para. 1 of the Patent Law refers not only to sequences of human origin, but</p>

	<p>sequence or partial sequence of a gene may, however, be patented as an invention if they are produced by means of a technical process, their function is specifically indicated, and the further requirements of Article 1 are fulfilled; Article 2 remains reserved.</p>	<p>also to those of animal or plant origin.</p> <p>In contrast, sequences which are derived from a naturally occurring sequence can be patentable (Art. 1b para. 2 of the Patent Law). By "derived sequence" is meant any sequence which is obtained from a sequence or partial sequence of a gene and which is functionally equivalent to that. Therefore it includes, in particular cDNA, RNA, polypeptides and proteins.</p> <p>In case of derived sequences a patentable invention is recognized only if the sequences have been isolated or obtained in some other way by a technical process. However, this alone does not justify the existence of an invention, there must also be a function disclosed in a credible way in the description. Since this function is part of the invention, it must be contained in the documents as filed (see. Art. 49 para. 2 lett. b PatG (Patent Law)). If there is no indication of a function at the filing date, the patent application must be dismissed (after appropriate threats)</p> <p>The term "function" describes any property of the sequence that causally contributes to a result usable in the art. If a derived sequence of a gene is used to produce a protein (or a portion of a protein), it is not only required to disclose this protein, but also its function. When a nucleotide sequence is not used for the production of a protein, the function to be indicated could for example be that the sequence has a specific transcriptional promoter activity. Providing mere general and speculative information on said function is not sufficient. They must be sufficiently specified, be substantial and credible. As part of the examination additional information or documents can be requested based on Art. 13 VwVG (Administrative Procedural Law) to enable the required assessment of the function.</p> <p>The protection by a claim of a nucleotide sequence derived from a gene sequence is limited to the sequence sections which perform the function described in the patent. The wording of Art. 8c PatG (Patent Law) shows that this does not affect the amino acid sequences. In order to render the scope of protection clear in case of derived nucleotide sequences, the patent applicant must provide (if necessary as part of the examination), which sequence sections are functionally</p>
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			relevant. Not relevant sequence segments shall be deleted from the claims, either by the applicant or by the examiner.
CY	NO		NO
CZ	NO	<p>In the patent legislation, there are not any specific legal provisions related to this issue. However, in respect to the general patentability principle, the industrial applicability of DNA sequences must be fully disclosed in the patent application.</p> <p>Excerpts from ACT No. 206/2000 Coll. of 21 June 2000 on the Protection of Biotechnological Inventions and on the Amendment to Act No. 132/1989 Coll., on the Protection of Rights to New Plant and Animal Varieties, as amended by Act No. 93/1996 Coll.:</p> <p>Section 3 Exclusions of patentability Patents shall be not granted to [...] b) human body at various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene; it does not apply to an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element, and [...]</p> <p>Section 5 Special provisions on the application of biotechnological invention [...] (8) If the application concerns an invention of the sequence or partial sequence of a gene, their industrial applicability must be made obvious in the patent application.</p>	NO. The Examination Guidelines do not mention purpose/function limited protection for sequences at all.
DE	YES	The German patent law foresees the following (implementation of Article 5(3) of the Biotech Directive):	The official guidelines for examination do not contain anything concerning the cited provisions since the last update is still from 2004 and the biotech directive was implemented into the German patent law

		<p>Section 1a [...]</p> <p>(3) The industrial application of a sequence or partial sequence of a gene shall be disclosed in the application specifying the function performed by the sequence or partial sequence.</p> <p>(4) If the invention concerns a sequence or partial sequence of a gene whose structure corresponds to that of a natural sequence or partial sequence of a human gene, the patent claim shall include its use for which industrial application is disclosed pursuant to subsection (3).</p>	<p>only in 2005.</p> <p>There is an English leaflet "Information for Patent Applicants" (2014 edition) available from the internet set of the German Patent and Trademark Office containing the following statements:</p> <p>"I.5 (What is capable of being protected? / Industrial Application) [...] The industrial application of a sequence or a partial sequence of a gene must be disclosed in the application specifying what function the sequence or partial sequence performs. If the structure of a sequence or a partial sequence of a gene is identical to the structure of a natural sequence or partial sequence of a human gene, its use shall be included in the patent claim (Sec. 1a (3) and (4) Patent Act)."</p> <p>"VI.2.1 (Documents to submit / Application documents / Claims) [...] If the sequence or partial sequence of a gene, having a structure identical to the structure of a natural sequence or partial sequence of a human gene, is the subject matter of the invention, the patent claim shall include its use, for which the industrial application has been disclosed under Section 1a (3) of the Patent Act."</p> <p>"VI.2.2 (Documents to submit / Application documents / Description) [...] The industrial application of a sequence or partial sequence of a gene shall be disclosed in the application specifying what function the sequence or partial sequence performs (Sec. 1a (3) Patent Act)."</p>
DK	NO	<p>There is no purpose/function limited protection in Denmark. Consequently, full product protection can be enjoyed.</p> <p>Excerpts from the Danish patent law:</p> <p>1a.-(1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.</p> <p>(2) Notwithstanding subsection 1 an element isolated from</p>	<p>The patent office has also NOT issued any guidelines in respect of that.</p>

		the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.	
EE	NO	<p>Excerpts from the Estonian Patent Act (Act No. RT I 1994, 25, 406, as last amended by Act No. RT I, 28.12.2011,1):</p> <p>§ 6. Subject of invention [...] (2) The following, inter alia, are not regarded as the subject of inventions: 1) discoveries, including descriptions of the formation or development of the human body or sequence or partial sequence of human gene, scientific theories and mathematical methods; [...]</p>	NO
ES	NO	<p>According to art 5 of the Spanish patent law (ley de Patentes) genes are patentable, and claims directed to DNA sequences do not need to be limited to their function. The only requirement is that the function should be explicitly disclosed in the application (description is enough). There is also a new law coming into force on 1 April 2017, but the provisions concerning this point are the same.</p>	<p>The guidelines of the Spanish Patent Office (part E) state that the function has to be described in the application. In that case the DNA sequence as such is patentable. The relevant part of these guidelines reads:</p> <p>The industrial application of a total or partial sequence must be explicitly disclosed in the patent application at the time of filing. Hence, a DNA fragment without any indication of a particular function is not considered patentable. However, a DNA fragment for which a particular function is indicated, for example to be used as a probe for disease diagnostic, is considered patentable, unless there are other reasons for its rejection.</p>
FI	NO	<p>There is no purpose/function limited protection for nucleic acid sequences in patent legislation in Finland. The patenting of DNA sequences, RNA sequences and amino acid sequences requires that their industrial use is disclosed in the application.</p> <p>Excerpts from the Patents Act:</p> <p>CHAPTER 1, General Provisions</p>	<p>NO. In the guidelines (Handbook, "Patenttikäsikirja", I.2.2. p. 137) it reads:</p> <p>The patenting of DNA sequences, RNA sequences and amino acid sequences requires that the sequence and the industrial use is disclosed in the application.</p>

		<p>Section 1a (30.6.2000/650) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.</p> <p>An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may, without prejudice to the provisions of subsection (1), where the requirements for patentability are fulfilled, constitute a patentable invention, even if the structure of that element is identical to that of a natural element.</p>	
FR	YES	<p>The protection of an isolated DNA sequence is limited to its identified function. The purpose/function limited protection provided in the French law relates to human genes and sequences, i.e. is not said to apply to all types of organisms.</p> <p>Article L613-2-1 of the Intellectual Property Code provides that the scope of a claim concerning a gene sequence shall be confined to the part of such sequence that is directly related to the specific function disclosed concretely in the description. Although this article does not specify that the sequence is human it has to be noticed that this provision has been introduced in the law on 6 August 2004 in the same amendment than the article L.611-18 which targets specifically human sequences.</p> <p>In practice, a claim directed to a gene sequence is considered as being limited to the technical application of a specific function associated with said sequence. In other words, the scope of a claim directed to a gene sequence will not be that of a product claim per se but rather the product for its specific disclosed function(s).</p> <p>To the best of our knowledge, there is no case law in France to illustrate this point.</p> <p>Excerpts from the Intellectual Property Code:</p>	<p>The French patent office has not issued specific guidelines regarding the patentability of DNA sequences. However, the French Examination guidelines contain a small paragraph regarding this point (Paragraph 2.3 (4); Page 116):</p> <p><i>(4) les séquences totales ou partielles d'un gène prises en tant que telles. Les inventions portant sur des éléments (éléments intrinsèques, tels que les cellules, protéines, ADN, divers métabolites) ou des produits (excrétas, tels que a sueur et l'urine) d'origine humaine, sont également considérées comme non brevetables, lorsque ces éléments et produits sont considérés en tant que tels, c'est à dire :</i></p> <p><i>lorsque ces éléments ou produits sont présentés tels qu'ils se retrouvent dans la nature, en interaction avec leur environnement naturel. Par exemple un fragment d'ADN non isolé, tel qu'il se trouve intégré dans la totalité du génome humain. Breveter un tel AND non isolé, reviendrait à breveter le génome humain lui-même.</i></p> <p><i>lorsque ces éléments ou produits ont été simplement isolés et chimiquement caractérisés, alors qu'aucune fonction ou application industrielle n'a encore été identifiée. C'est le cas notamment d'un fragment d'ADN isolé dont on a déterminé la séquence, alors que l'on ne connaît pas le produit pour lequel cet ADN code ni, a fortiori, la fonction de ce dernier qui pourrait permettre d'en envisager une application pratique dans l'industrie (thérapeutique, agrochimique, etc.).</i></p>

		<p>Article L611-18 (inserted by Act No. 2004-800 of 6 August 2004, Article 17a II, Official Journal of 7 August 2004):</p> <p>The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. Only an invention constituting a technical application of a function of an element of the human body may be protected by a patent. This protection shall cover the element of the human body only to the extent necessary to the realization and the exploitation of this particular use. Such use must be disclosed in the patent application in a concrete and precise manner. The following, in particular, shall be considered unpatentable: [...] d) total or partial sequences of a gene as such.</p> <p>Article L613-2-1(inserted by Act No. 2004-800of 6 August 2004, Article 17 a III, Official Journal of 7 August 2004):</p> <p>The scope of a claim concerning a gene sequence shall be confined to the part of such sequence that is directly related to the specific function disclosed concretely in the description. The rights created by the grant of a patent including a gene sequence may not be called upon against a later claim on the same sequence if this claim satisfies the requirements of Article L. 611-18 and if it discloses any other particular application of this sequence.</p>	<p><i>En revanche une invention portant sur un élément isolé du corps humain ou autrement produit par un procédé technique, et qui est susceptible d'application industrielle, n'est pas exclue de la brevetabilité, même si la structure de cet élément isolé est identique à celle d'un élément naturel. En effet, cet élément isolé est par exemple le résultat de procédés techniques l'ayant identifié, purifié, caractérisé et multiplié en dehors du corps humain, techniques que seul l'homme est capable de mettre en oeuvre et que la nature est incapable d'accomplir par elle-même (considérants 20 et 21 de la Directive 98/44/CE).</i></p> <p>These guidelines confirm the fact that the function and the technical application of a DNA sequence have to be clearly disclosed so as to render this sequence patentable. The first example concerns a non-isolated DNA fragment (i.e. such as integrated in the human genome). According to the guidelines such a DNA fragment is not patentable. The second example concerns the situation where a DNA fragment has been isolated and sequenced but the product of this sequence is not known and a fortiori its function is also not known. According to the guidelines such a DNA fragment is also not patentable.</p>
GB	NO	<p>Isolated nucleic acid sequences may be patented, so long as the industrial application of the sequence is disclosed in the application as filed. However, for this protection to extend to propagated material, the genetic information must perform its function.</p> <p>Excerpt from Schedule A2, introduced by s76A UKPA:</p>	<p>No, the Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office issued in 2013 do not consider purpose or function limited protection for nucleic acid sequences. The Guidelines only confirm that the industrial application of nucleic acid sequences is required for patentability:</p> <p>55. Where the invention resides in a sequence or partial sequence of a gene, paragraph 6 of Schedule A2 to the Act additionally requires</p>

		<p>BIOTECHNOLOGICAL INVENTIONS</p> <p>[...]</p> <p>3. The following are not patentable inventions –</p> <p>(a) the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;</p> <p>[...]</p> <p>5. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.</p> <p>6. The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application as filed.</p> <p>[...]</p>	<p>disclosure in the application as filed of the industrial application of that gene. The absence of this disclosure in an application when filed would seem to be fatal to that application.</p> <p>103. Paragraph 2 of Schedule A2 to the Patents Act 1977 permits biological material which is isolated from its natural environment or produced by means of a technical process to be the subject of an invention even if it previously occurred in nature. Paragraph 5 of Schedule A2 similarly states that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may also constitute a patentable invention, even if the structure of that element is identical to that of a natural element.</p> <p>104. However, in line with section 1(2)(a) of the Patents Act and Paragraph 3(a) of Schedule A2, the simple discovery of biological material, eg a human gene, is not patentable. This is the situation that applies when a gene sequence is known simply as a sequence, possibly as part of the genome or in an isolated state. In that sense it is a discovery; nothing more is known about it other than that it exists as a piece of information.</p>
GR	NO	<p>In Greece there is no other legislation regarding biotechnology and genetic engineering except the adaptation to Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (Presidential Decree 321/2001).</p> <p>Excerpts from PRESIDENTIAL DECREE No. 321/24.09.2001:</p> <p>Article 4</p> <p>1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.</p> <p>2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence of partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.</p>	<p>The Greek patent office has not published any kind of guidelines for examination of purpose/function limited protection for nucleic acid sequences.</p>

		3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.	
HR	NO	<p>Excerpts from the Croatian Patent Law:</p> <p>EXCLUSION FROM PATENTABILITY</p> <p>Article 6</p> <p>Excluded from patent protection shall be:</p> <p>[...]</p> <p>2. the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene. An invention relating to an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application as originally filed.</p>	<p>According to the Section B-II 2.2. of the Guidelines for examination of the patent application:</p> <p>2.2 Sequences and partial sequences of genes</p> <p>In general it is required that the description of a Croatian patent application should, where this is not self-evident, indicate the way in which the invention is capable of exploitation in industry. In relation to sequences and partial sequences of genes, this general requirement is given specific form in that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. A mere nucleic acid sequence without indication of a function is not a patentable invention (EU Dir. 98/44/EC, rec. 23). In cases where a sequence or partial sequence of a gene is used to produce a protein or a part of a protein, it is necessary to specify which protein or part of a protein is produced and what function this protein or part of a protein performs. Alternatively, when a nucleotide sequence is not used to produce a protein or part of a protein, the function to be indicated could e.g. be that the sequence exhibits a certain transcription promoter activity.</p>
HU	NO	<p>The industrial applicability of a sequence or a partial sequence of a gene must only be disclosed in the patent application.</p> <p>Excerpts from ACT XXXIII OF 1995 on the protection of inventions by patents:</p> <p>Patentable biotechnological inventions</p> <p>Article 5/A</p> <p>[...]</p> <p>(3) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.</p> <p>(4) An element isolated from the human body or otherwise produced by means of a technical process, including the</p>	<p>NO. There is nothing in the Guidelines concerning the purpose/function of patentable sequences.</p>

		<p>sequence of partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.</p> <p>Disclosure of the invention, the claims and the abstract</p> <p>Article 60 (1) A patent application shall disclose the invention in a manner sufficiently clear and detailed for it to be carried out by a person skilled in the art on the basis of the description and the drawings. The industrial applicability of a sequence or a partial sequence of a gene shall be disclosed in the patent application. [...]</p>	
IE	NO	<p>No, there is no limitation on protection. However, as per The European Communities (Legal Protection of Biotechnological Inventions) Regulations 2000 (which implements EU Directive 98/44/EC) Section 5(3) "If an invention concerns the sequence or partial sequence of a gene the industrial application thereof shall be disclosed in the patent application as filed".</p> <p>Excerpt from S.I. No. 247/2000 - European Communities (Legal Protection of Biotechnological Inventions) Regulations, 2000:</p> <p>5. (1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, shall not be patentable. (2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. (3) If an invention concerns the sequence or partial sequence of a gene the industrial application thereof shall be disclosed in the patent application as filed.</p>	No, there are no Irish Patent Office examination guidelines.
IS	NO	There is no limitation on claims scope stipulated by the	No, there are no such guidelines in Iceland.

		<p>Icelandic Patent Act, but the Regulation on Patents No. 477/2012, with amendments (valid from 11 October 2013) stipulates that “If an invention concerns a gene, how the nucleotide sequence or part of the sequence can be utilised commercially must be specified.”</p> <p>Excerpt from the Icelandic Patent Act No. 17/1991, including all amendments:</p> <p>Article 1 a (Act No. 22/2004, Art. 2 (a) (Valid from May 11 2004)): The human body in its various stages of formation or development and the mere discovery of any of its elements, such as nucleotide sequences or partial nucleotide sequences of genes, cannot be considered patentable inventions. Notwithstanding Paragraph 1, an element of the human body, including a nucleotide sequence or partial nucleotide sequence of a gene, which is isolated from the body or produced in another way by a technical process may be considered a patentable invention even if the structure of such an element is identical to the structure of a natural element.</p> <p>Excerpt from the Regulation on Patents No. 477/2012, with amendments (valid from 11 October 2013):</p> <p>Art. 13 Description [...] If an invention concerns a gene, how the nucleotide sequence or part of the sequence can be utilised commercially must be specified. [...]</p>	
IT	YES	<p>Italian Industrial Property Code foresees the following (implementation of Articles 5 of EU Biotech Directive):</p> <p>Art. 81 quarter(1)(d) IPC states that function and industrial applicability must be concretely indicated and described for</p>	No Guidelines made by Italian Patent Office.

	<p>an element isolated from the human body or otherwise produced by means of a technical process.</p> <p>Art. 81 quinquies(1)(c) IPC states that the specific function, which has to be industrially applicable, of a gene or fragments thereof must be indicated, described and specifically claimed.</p> <p>Excerpts from the ITALIAN CODE OF INDUSTRIAL PROPERTY (Legislative Decree N°30 of 10 February 2005, Text effective as from 2 September 2010, as amended by Legislative Decree N°131 August 2010):</p> <p>Section IV-bis Biotechnological Inventions</p> <p>81-quater. Patentability. 1. The following may be patented provided that they meet the requirements of novelty and inventive step and are susceptible to industrial application: [...] d) an invention relating to an element isolated from the human body or produced otherwise, through a technical process, even if its structure is identical to that of a natural element, provided that its function and industrial application are concretely indicated and described. A technical process is understood as a process which only human beings are capable of carrying out and that nature by itself is not able to perform; [...]</p> <p>81-quinquies. Exclusions. 1. Subject to the exclusions set forth in Article 45(4), the following may not be patented: a) the human body, from the moment of conception and in the various stages of its development, nor the mere discovery of one of the elements of the body itself, including the sequence or partial sequence of a gene, in order to guarantee that patenting rights are exercised with respect</p>	
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		<p>for the fundamental rights and integrity of man and the environment; [...]</p> <p>c) a simple DNA sequence, a partial sequence of a gene, used to produce a protein or a partial protein, unless an indication and description is provided of a function useful for evaluation of the requirement of industrial application and the corresponding function has been specifically claimed; each sequence is considered independent for patent purposes in the event of sequences that overlap only in the parts not essential to the invention. [...]</p>	
LI	NO	See under "CH"	
LT	NO	<p>No purpose/function limited protection for DNA sequences is specially mentioned in Lithuanian Patent law.</p> <p>Excerpt from THE REPUBLIC OF LITHUANIA PATENT LAW 18 January 1994 No. I-372, Vilnius (as last amended on 23 December 2010 by Law No. XI-1261):</p> <p>Article 4. Patentable Inventions Patents shall be available for any inventions in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. The following shall not be regarded as inventions: [...]</p> <p>5) existing in a natural environment the human body or its element, including the sequence or partial sequence of a gene, at the various stages of its formation and development. This provision shall not apply to an element isolated from the human body or otherwise produced by means of a technical process, as well as to the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element [...]</p>	<p>NO</p> <p>Correspondingly examination of purpose/function limited protection for DNA sequences is not specified in national Guidelines for examination. (Regulations on Submission, Examination of Patent Applications and Issuance of Patent)</p>
LU	not clear	The industrial applicability of gene sequences must be mentioned in the application in order to meet the requirement of industrial applicability.	NO

		<p>Excerpt from the Law of July 20, 1992 Amending the System for Patents for Invention, as amended by the Law of April 7, 2006:</p> <p>Art. 5ter</p> <p>1) The human body, at the various stages of its formation and development, including germ cells, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.</p> <p>2) An isolated element of the human body or otherwise produced by a technical process, including the sequence or the partial sequence of a gene, can constitute a patentable invention, even if the structure of this element is identical to that of a natural element.</p> <p>3) Only an invention constituting a technical application of a function of an element of the human body may be protected by a patent. This protection shall cover the element of the human body only to the extent necessary to the realization and the exploitation of this particular use. Such use must be disclosed in the patent application in a concrete and precise manner.</p>	
MC	NO		NO
MK	NO	<p>There is NO purpose/function limited protection of nucleic acid sequences in the patent legislation of Macedonia.</p> <p>Excerpt from the LAW ON INDUSTRIAL PROPERTY:</p> <p>Patentable inventions</p> <p>Article 25</p> <p>[...]</p> <p>(3) An invention shall not be considered as invention within the meaning of paragraphs (1) and (2) of this Article if it is:</p> <p>[...]</p> <p>4) human body in different stages of its formation and development or simple discovery of one of its elements, including a sequence or a partial sequence of a gene.</p> <p>[...]</p>	<p>The Macedonian patent office does not perform substantive examination. Consequently, there are NO guidelines for examination of purpose/function limited protection for nucleic acid sequences.</p>

		<p>5) Element which is isolated from the human body or produced by means of a technical process containing a sequence or a partial sequence of a gene may also be protected by a patent when the structure of that element is identical with the one of the natural element, whereby the industrial applicability must be contained in the description of invention included in the application form. [...]</p>	
MT	NO	<p>Isolated nucleic acid sequences may be patented, so long as the industrial application of the sequence is disclosed in the application as filed.</p> <p>Excerpts from the Patents and Designs Act, Cap 417 Laws of Malta:</p> <p>Art. 4 [...] (5) A patent shall not be granted in respect of: [...] the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene: Provided that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element; [...]</p> <p>Art. 15 [...] (2) (a) Where an application refers to an element isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequence of a gene, the industrial application of a sequence or a partial sequence of a gene must be</p>	NO

		disclosed in the patent application. (b) When the application concerns a sequence or a partial sequence of a gene used to produce a protein or part of a protein, it is necessary to specify which protein or part of protein is produced or function or sequence it performs. [...]	
NL	NO	<p>A function/use of nucleic acid and/or protein sequences must be mentioned in the application in order to meet the requirement of industrial applicability. No need to include this in the claim.</p> <p>Excerpts from the Dutch Patent Act:</p> <p>Article 2a [...] 2. Invention referred to in paragraph 1 at least include inventions concerning: [...] b. a part of the human body that is isolated or obtained otherwise via a technical process, including the sequence or a partial sequence of a gene, even if the structure of that element is identical to that of a natural element; [...]</p> <p>Article 3 1. No patent shall be issued for: [...] b. the human body in its various stages of its formation and its development, as well as the sole discovery of one of its parts, including a sequence or partial sequence of a gene; [...]</p> <p>Article 25 [...] 3. If an invention relates to a sequence or partial sequence of a gene, the description shall contain a concrete description of the function and the industrial application of that sequence or partial sequence. In the event that a sequence or a partial sequence of a gene is used for the</p>	NO, the patent office guidelines do not say anything about purpose/function limitation of claims.

		production of a protein or partial protein, the description of the industrial applicability shall contain a specification of the protein or partial protein that has been produced and its function. [...]	
NO	NO	No, there is no explicit purpose/function limitation in the Norwegian Patent Act. Excerpt from the Norwegian Patents Act: Section 1 a. The human body, at all of the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. An element which is isolated from the human body or otherwise produced by means of a technical process, including the sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a naturally existing element.	The Guidelines contain a general requirement that the industrial applicability of the invention should be disclosed in the application: 3.3.7 Industrial applicability The description shall explicitly state how the invention shall be utilised industrially, if this is not obvious from the description of the invention or it immediately is evident from the nature of the invention (see T870/04). In view of the broad meaning of the term “which is industrial applicable” in the patent Act section 1, 1st paragraph, see chapter IV, point 3.1.[Guidelines], it must in most cases be expected that how the invention is industrial applicable will be self-explanatory such that an explicit description of this is not necessary. But it may be cases, e.g. concerning methods for testing, where the industrial applicability is not obvious and where this if that is the case must be clarified.
PL	not clear	According to Article 93 ² of recently amended Polish Industrial Property Law which came into force on December 1, 2015: [...] 2. In a patent application concerning a sequence or a partial sequence of a gene, the industrial application of the sequence must be disclosed in the patent description, and additionally its function is to be indicated in the independent patent claim. 3. In order to fulfil the industrial applicability criterion in a case of use of a sequence or a partial sequence of a gene for production of a protein or a protein part, it is to be defined in the description of the invention which protein or which part thereof is produced and what is their function.	No. There are no Guidelines for Examination in Poland of purpose/function limited protection for nucleic acid sequences.
PT	NO	The Portuguese Industrial Property Code does not specifically mention limitations to the protection of nucleic acid sequences.	However, the guidelines for examination of the Portuguese Patent Office include some provisions related to this matter:

		<p>Only Article 54(c) refers to the specific case of sequences or partial sequences of genes:</p> <p>Article 54 Special cases of patentability</p> <p>1. The following shall be patentable: [...]</p> <p>c) A new invention, involving an inventive step and being susceptible of industrial application, concerning any element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element, provided that the industrial application of a sequence or partial sequence of a gene is expressly stated and specifically explained in the patent application; [...]</p>	<p>1.5.1.3 Protection of DNA sequences</p> <p>For the DNA sequence of an organism or for a protein found in nature, it will be necessary to find an industrial application. The clarification of the function of the respective DNA/protein sequence may be sufficient, but it must be based on viable methods, such as functional studies (Article 57 EPC) and only in this way will it be possible to patent one or more genes or portions thereof. In these cases, a sequence of nitrogenous bases (A, G, C and T) must be provided, which is to be inserted in programmes for this purpose (e.g. http://www.ncbi.nlm.nih.gov/blast/Blast.cgi) so that it will be aligned with the genome sought and make it possible to assess the criteria of novelty and/or inventive step. For this purpose, it is important that this sequence be submitted in digital format.</p>
RO	NO	<p>No purpose/function limited protection for nucleic acids sequences, but Romanian Patent Law 64/1991 requires that its industrial application be disclosed in the patent application.</p> <p>Excerpts from Law No. 64/1991 on Patents (as amended up to Law No. 83/2014):</p> <p>Chapter II - Patentable Inventions</p> <p>Art. 6 [...]</p> <p>(2) Inventions in the field of biotechnology shall be patentable if they relate to: [...]</p> <p>d) an element isolated from the human body or otherwise produced by a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element.</p> <p>Art. 8</p>	<p>There are no Guidelines for Examination in Romania, but The Implementing Regulation of the Patent Law 64/1991, also mentions in art 72(3) that:</p> <p>The industrial applicability of a sequence or of a partial sequence of a gene shall be concretely disclosed in the patent application, by indicating the specific function of the sequence or partial sequence.</p>

		<p>(1) Patents shall not be granted under this Law in respect of: [...]</p> <p>c) the inventions having as a subject-matter the human body in its various stages of formation and development, as well as the mere discovery of one of its elements, including the sequence or partial sequence of a gene; [...]</p> <p>Art. 12 [...]</p> <p>(2) The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application.</p>	
RS	NO	<p>Excerpts from The Patent Law:</p> <p>Human Body and its Elements</p> <p>Article 8 The human body, at any stage of its formation and development, and the simple discovery of one of its elements, including sequences or partial sequences of genes, shall not be regarded as invention that can be protected by a patent. An element isolated from the human body or produced by means of a technical process, including the sequences or partial sequences of genes, may be patentable, even where the structure of that element is identical to that of a natural element. The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application on the day of its filing.</p>	NO, the examination Guidelines do not concern purpose/function limited protection for patentable sequences.
SE	NO	<p>A function/use must be given in order to meet the requirement of industrial applicability, but this use does not have to be included in the claim and does not, arguably, limit the protective scope of a claim.</p> <p>Excerpts from The Patents Act:</p>	<p>NO, the patent office guidelines do not say anything about purpose/function limitation of claims.</p> <p>Excerpt from the Guidelines:</p> <p>B5, 3.2 [...] In order for a DNA sequence or partial sequence of a gene to be patentable, the application must specify how it is susceptible of</p>

		<p>Article 1 b. The human body at the various stages of its formation and development, as well as the mere discovery of one of its elements, including the sequence of a gene or a partial sequence of a gene, cannot constitute a patentable invention.</p> <p>An isolated element of the human body or an element otherwise produced by means of a technical process, including a gene sequence or a partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical with that of a natural element. (Act 2004:159).</p> <p>Article 8, second paragraph: [...] If the invention relates a gene sequence or a partial sequence of a gene, the application must, however, always indicate how the invention can be applied industrially. The description shall be sufficiently clear for it to be carried out by a person skilled in the art with the guidance thereof. [...] (Act 2014:289)</p>	<p>industrial application (see § 8 PL of the second paragraph fourth sentence). For example, if a sequence or portion of a gene sequence is to be used to produce a protein, the description should specify which protein that is to be produced, and which function the protein shall exercise.</p>
SI	NO	<p>The industrial applicability of gene sequences must be mentioned in the application in order to meet the requirement of industrial applicability.</p> <p>Excerpt from the Decree on the Legal Protection of Biotechnological Inventions:</p> <p>Article 5 (1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. (2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. (3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent</p>	NO

		application.	
SK	NO	<p>However, the industrial applicability of DNA sequences has to be described in the patent application.</p> <p>Excerpts from Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts as Amended (The Patent Act, consolidated version 2009):</p> <p>Article 5 Patentability of inventions [...] (2) Patents pursuant to paragraph 1 shall be also granted for biotechnological inventions concerning to a product consisting of or containing biological material, or to a process by means of which biological material is produced, processed or utilised, including cases when invention relates to [...] d) an element isolated from a human body or produced by other means of a technical process, including a sequence or partial sequence of a gene also in the case when the structure of such element is identical with a structure of a naturally existing element. [...]</p> <p>Article 6 Exceptions to patentability (1) Patents shall not be granted to [...] d) inventions relating to human body in different stages of its formation or development or relating only to discovery of some elements of human body, including sequences or partial sequence of a gene, with an exception pursuant to Article 5(2)(d), [...]</p> <p>Article 38 Special provision on application of biotechnological</p>	NO, the examination Guidelines do not concern purpose/function limited protection for patentable sequences.

		<p>invention [...]</p> <p>(7) If a sequence or partial sequence of a gene is a subject-matter of an application, industrial applicability of an invention must be explained in the application. [...]</p>	
SM	NO	<p>There is no purpose/function limited protection in San Marino.</p> <p>Excerpt from LAW n. 79 of 25 May 2005 - Industrial Property Consolidation Act:</p> <p>Article 2 (Subject-matter of the patent and exclusions from patentability) [...]</p> <p>4. The following inventions are not patentable: [...]</p> <p>d) inventions concerning the human body, at all of the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene. [...]</p>	<p>The patent office has also NOT issued any guidelines in respect of that.</p>
TR	NO	<p>There is not any limitation or any case law related to this subject.</p>	<p>No. The Turkish Patent Institute does not have any guidelines for examination of purpose/function limited protection for DNA sequences.</p>

Annex C2: Technological Background

Figure 1

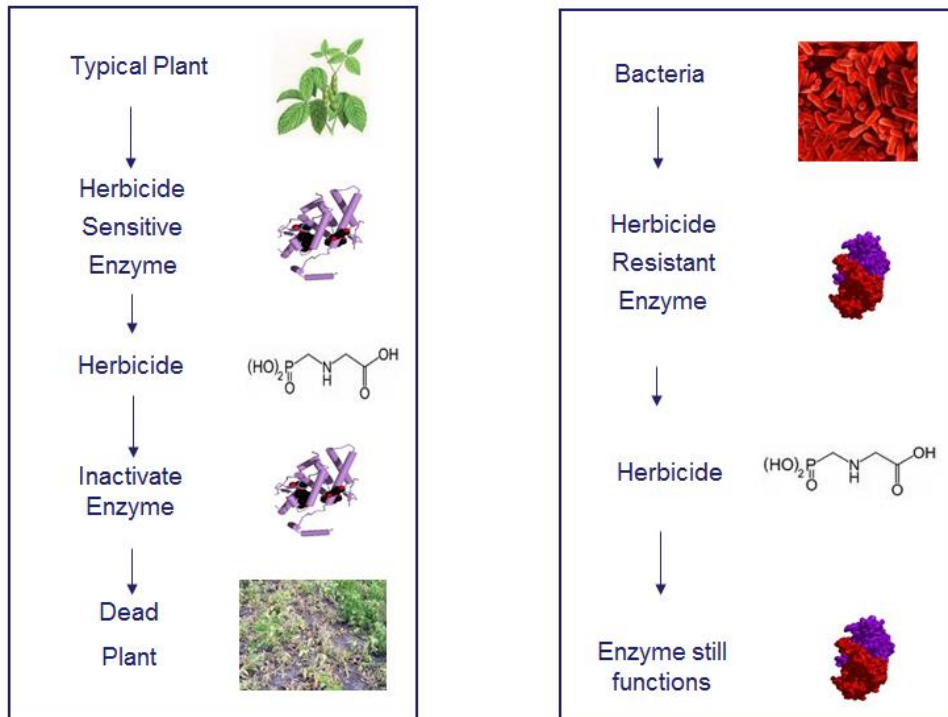


Figure 2

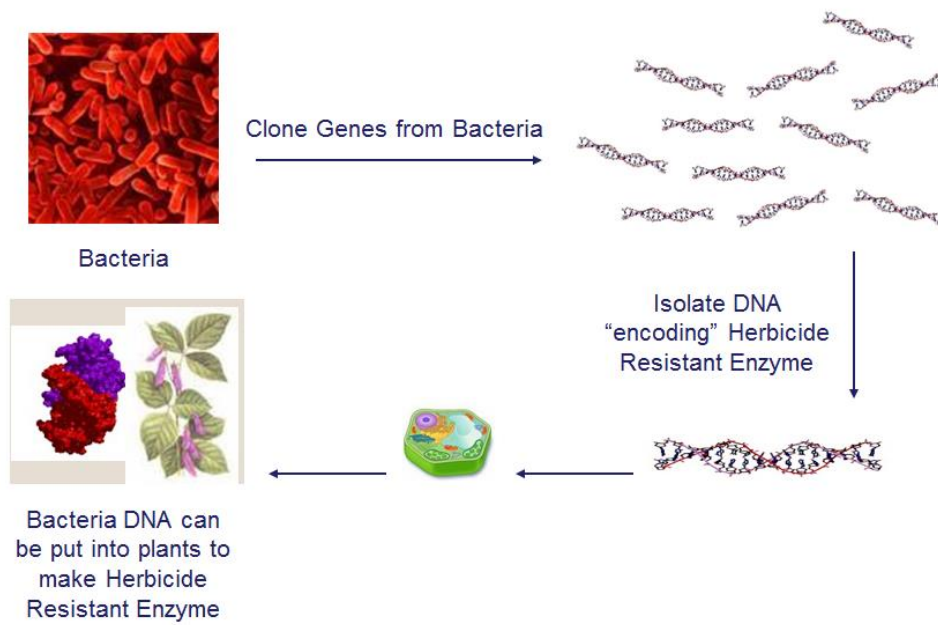
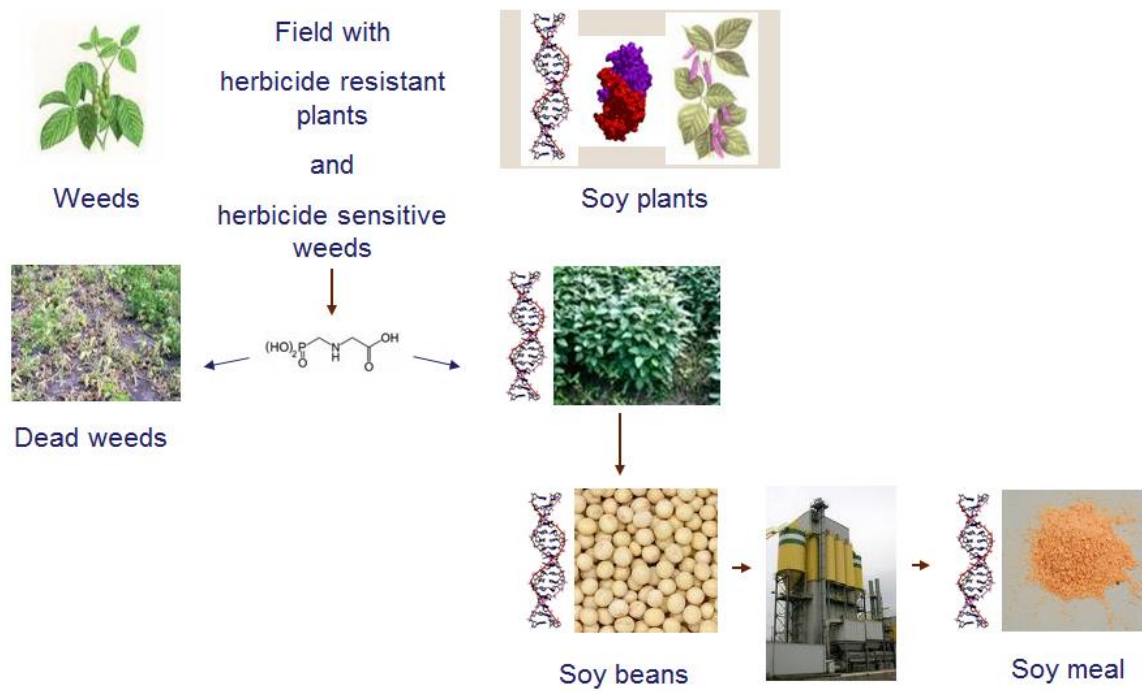


Figure 3



Annex C3: Independent Claims of EP 546 090 (Monsanto)

1. An isolated DNA sequence encoding a Class II EPSPS enzyme, said enzyme being an EPSPS enzyme having a Km for phosphoenolpyruvate (PEP) between 1-150 pM and a Ki(glyphosate)/Km(PEP) ratio between 3-500, which enzyme is capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3 and SEQ ID NO:5.

4. An isolated DNA sequence encoding a protein which exhibits EPSPS activity wherein said protein is capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3 and SEQ ID NO:5.

7. A recombinant, double-stranded DNA molecule comprising in sequence:

a) a promoter which functions in plant cells to cause the production of an RNA sequence;

b) a structural DNA sequence that causes the production of an RNA sequence which encodes a Class II EPSPS enzyme capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID No:3 and SEQ ID No:5; and

c) a 3' non-translated region which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate tolerance of a plant cell transformed with said DNA molecule.

14. A method of producing genetically transformed plants which are tolerant toward glyphosate herbicide, comprising the steps of:

a) inserting into the genome of a plant cell a recombinant, double-stranded DNA molecule comprising:

i) a promoter which functions in plant cells to cause the production of an RNA sequence,

ii) a structural DNA sequence that causes the production of an RNA sequence which encodes a 5 fusion polypeptide comprising an amino terminal chloroplast transit peptide and a Class II EPSPS enzyme capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3 and SEQ ID NO:5,

iii) a 3' non-translated DNA sequence which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate tolerance of a plant cell transformed with said gene;

b) obtaining a transformed plant cell; and

c) regenerating from the transformed plant cell a genetically transformed plant which has increased tolerance to glyphosate herbicide.

20. A glyphosate tolerant plant cell comprising a DNA molecule of Claims 8, 9, 12 or 13.

28. A method for selectively controlling weeds in a field containing a crop having planted crop seeds or plants comprising

the steps of:

a) planting said crop seeds or plants which are glyphosate tolerant as a result of a recombinant double-stranded DNA molecule being inserted into said crop seed or plant, said DNA molecule having:

a promoter which functions in plant cells to cause the production of an RNA sequence,

ii) a structural DNA sequence that causes the production of an RNA sequence which encodes a polypeptide which comprises an amino terminal chloroplast transit peptide and a Class II EPSPS enzyme capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3 and SEQ ID NO:5,

iii) a 3' non-translated DNA sequence which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate tolerance of a plant cell transformed with said gene: and

b) applying to said crop and weeds in said field a sufficient amount of glyphosate herbicide to control said weeds without significantly affecting said crop.

Annex C4. Claims from DE 103 06 085 B4, DE 102 41 553 B4, DE 199 58 198 B4, DE 10 2004 004 924 B4 and DE 199 55 576 B4

Claim 1 of DE 103 06 085 reads:

1. A nucleic acid molecule encoding AKAP having the nucleotide sequence of SEQ ID NO:1 and all homologues with at least 83% that are functional analogues of the nucleic acid molecule having the nucleotide sequence of SEQ ID NO:1 for detection of an AKAP-PKA interaction or an AKAP and/or PKA inhibitor or a membrane permeable peptide.

Claim 1 of DE 102 04 924 reads:

1. Nucleic acid molecule coding for a human Omi/HtrA2 protein that has genetic changes at amino acid positions 141 and/or 399 as compared to the wild type, as well as corresponding fragments thereof, for use in the diagnosis of Morbus Parkinson and/or a predisposition thereof and/or for use in localizing and/or testing of substances effective against Morbus Parkinson.

Claim 1 of DE 102 41 553 B4 reads:

1. Nucleic acid capable of being used ["verwendbar"] for the diagnosis of a vascular disease, cardiac disease, arteriosclerosis or cancer...." (emphasis added)

Claim 1 of DE 199 58 198 B4 reads:

1. Nucleic acid, characterized in that..., and which is suitable for ["welche...geeignet ist"] detection of the proliferation potential of a tumour cell. (emphasis added)

Claim 18 of DE 199 55 576 B4 reads:

18. Nucleic acid, or homologue thereof, coding for a transfer protein according to claims 7 or 8 or a transfer compound according to claim 10 or the carboxy-terminal end of the Ki-67 protein that is contained in a transfer compound according to one of the claims 9-14 for use as a medicament.

During Parliamentary debate in Germany, the following question was posed by a member to the Ministry of Justice²⁰⁵:

Are there legal means of limiting the scope of protection a granted European patent confers in Germany in the manner §1a(4) of the amended Act does?

The Answer to this question was as follows²⁰⁶:

²⁰⁵ Written question from Dr. Joachim Pfeiffer, member German Parliament (federal paper 15/4595); see Kilger et al, J. Pat. Trademark Off. Soc. 87(7): 559-601, 2005)

²⁰⁶ Written answer from 17.12.2004 from Alfred Hartenbach of the German Federal Government (federal paper 15/4595); see Kilger et al, J. Pat. Trademark Off. Soc. 87(7): 559-601, 2005)

In accordance with the EPC, the EPO determines the scope of protection finally and bindingly when it grants the European patent (see Art. 69 EPC). In view of such European patents, a limitation of the scope of compound protection may only be accomplished by change of the EPC or its implementing regulations respectively.

However, one expert noted that the German Parliament in its deliberations and final decision-making expressed the clear political will to restrict the scope of protection for DNA sequences to the function disclosed, and to cover not only patents granted by the German national patent office DPMA but also by the EPO, and argued that this restriction of scope would be effective for all the patents valid in Germany, irrespective of granting date. The Parliament expected this to be implemented by case law: Some members of parliament were of the opinion that a German Court in a respective DNA patent case would be bound to the German law which stipulates a functional restriction in scope. Thus, a so-called teleological reduction by the Court was expected by Parliament. As case law, this rule would then apply to all valid national DNA patents.²⁰⁷

²⁰⁷ The above stated legal view was brought forward in particular by Member of Parliament Margot von Renesse who was very influential in achieving the German compromise so that the implementation law could be passed. See Schneider, I. 2010: The European Patent System. Shifts in Governance through Parliaments and Civil Society (Das Europäische Patentsystem. Wandel von Governance durch Parlamente und Zivilgesellschaft), Frankfurt/New York, p. 432 and p. 506.

Annex C5. Majority view on absolute product protection for DNA

Several well-known considerations have been raised in the past with regard to the justification, or lack thereof, for absolute product protection of genomic DNA molecules. Some of these considerations, which are not considered valid by the majority (11/15) of the Experts are as follows:

1) Scope of protection versus contribution to the public.

Some parties have voiced the opinion that absolute product protection for genomic nucleic acid molecules would overly reward the patentee with a scope of protection that is beyond the patentee's contribution to the public.

However, the majority of the Experts are of the opinion that this argument is not convincing.

While a given genome, i.e. the complete set of chromosomes, of an organism is present in nature, the fact that a given genomic DNA sequence encodes for a protein or set of proteins or has some other function in an organism is not known. There is no "roadmap" that indicates where a particular gene is located, what its function is or how it might be applied in an industrial manner. Furthermore, it is inevitable that experiments must be conducted (expressing the gene, sequencing the gene comparing the gene to other genes, etc.) in order to determine the borders of the gene and the function of the gene. All this is not "discovery", but rather, must be considered as an invention since the localization of a gene and determination of its informational content and function is typically an extremely time consuming and expensive process that requires inventive activity. Hence, rewarding a patentee absolute product protection for a genomic DNA molecule is commensurate with the contribution to the public of localizing and identifying the borders and composition of the gene and identifying at least one function of a gene.

2) Special nature of genomic nucleic acids as carriers of genetic information.

Some parties have voiced the opinion that genomic DNA is different from other chemical substances because it encodes informational value that is hereditary.

However, the majority of the Experts are of the opinion that this argument is not convincing.

A genomic DNA molecule is no different from other chemical molecules. DNA is a polymer of nucleic acids. An isolated genomic DNA molecule does not exist in nature. The technical fact of the matter is that chemical bonds must be broken in order to isolate a portion of a genomic DNA molecule in order to isolate it. Moreover, many genes contain so-called introns and exons. The exons are regions of the gene that actually code for a protein, whereas the introns are "spliced" out of the gene when the gene is expressed as mRNA. Hence, many genes are typically expressed and cloned as a so-called cDNA molecule that contains only the coding exon regions of a gene and, therefore, does not exist in nature. Thus, providing this cDNA is similar to the provision of a traditional chemical substance that is not found in nature.

3) Possibility to "work around" a patent claim on genomic DNA.

Some parties have voiced the opinion that one cannot "invent around" a patented genomic DNA sequence, i.e. invent a different DNA sequence, because evolution has placed constraints on the structure of genes and only nucleic acids are capable of forming DNA and only the nucleic acids DNA

or RNA are capable of carrying genetic information to encode proteins – this cannot be done by some other chemical molecule.

However, the majority of the Experts are of the opinion that this argument is not convincing.

With regard to the concept that one cannot “invent around” a patent to a genomic DNA sequence, a third party is still free to invent an improved gene that encodes, for example, for a protein with a better activity than the original protein. In doing so, the third party makes use of the original patented gene and is dependent on the original patent. In addition, the cause and cure of disease is often very complex. While it is true that a certain defect in a gene may be identified as the main cause of a particular disease, and be patented, other mutations in a gene may also cause disease and can be found by a subsequent inventor. Furthermore, in order to develop a cure for any disease caused by a mutation in a gene, a third party is free to explore any mechanism of action and experiment with any traditional chemical substances to cure the disease. Finally, a patent will typically not just contain claims to genomic DNA. Rather, such patents will also include claims to cells expressing said gene, diagnosis of a disease caused by said gene, screening for compounds to treat said disease, etc., all of which are intended to protect a constellation of different concepts surrounding the gene and its newly found function. Limiting a claim to a gene to a particular function will not affect or diminish the scope of protection afforded by all these different types of claims.

It must also be noted here that many, if not all, EU countries have research exemptions either in their patent law or otherwise codified that permit third parties to conduct research using the patented product, here a genomic DNA molecule, without requiring the permission of the patentee.

4) Dependency of third parties on first patent to a given gene and encouragement/discouragement to research and legal certainty for third parties.

Some parties have voiced the opinion that limiting the scope of protection for genomic DNA molecules would encourage research. Moreover, limiting protection of a genomic DNA molecule to a given function would simplify the determination of whether a third party would infringe a patent claim to genomic DNA molecule with a particular function because each patent would be restricted to that function alone.

However, the majority of the Experts are of the opinion that these arguments are not convincing.

Limiting the scope of protection of a genomic DNA molecule to a particular function would not encourage research; it would discourage research because the patentee might feel that the limited scope of protection that might be awarded is not commensurate with the risk and amount of time and expense associated with doing the research to begin with.

Furthermore, it is an illusion to think that the limitation of claims to genomic nucleic acids to a particular function will insure legal certainty and would not prevent dependency of later patents on earlier patents. This can be illustrated using the following example. If one were to find that gene A is responsible for expressing protein A, then one might be able to obtain a patent to gene A that encodes and expresses protein A because the “function” of gene A can be seen in encoding protein A. However, in almost all cases protein A will interact and influence the behaviour of other substances, for example substance X, Y or Z. One could then obtain a patent for gene A for altering the behaviour of substances X, Y or Z because a “function” of gene A is to express protein A which

influence the behaviour of all of these substances. One could then find that substance X causes disease X*, that substance Y* causes disease Y and that substance Z causes disease Z*. Therefore, one could also obtain a patent to gene X for treating disease X*, Y*, or Z* because gene A is ultimately responsible for having this function as well. This sort of cascade is not something theoretical – the biology of genetic information is inherently complex and intertwined.

It can be seen on hand of this example that limiting the original patent to a gene having a certain function is problematic. What function is to be used to limit the scope of protection of the gene in this case: “encoding protein A”; “altering the behaviour of substances X, Y or Z” or “treating disease X*, Y*, or Z*”? This limitation does not lead to less legal certainty for any party.

It can also be seen on hand of this example that limiting the original patent to a gene having a certain function does not serve to clear a field for parties other than the original patentee because the subsequent patents would all still be dependent on the original patent because there is a causal chain from the first to the last patent that is unbroken – to cure disease X*, one must modulate protein X, but to modulate protein X, one must express protein A – all these steps are dependent on the expression of gene A and all of the subsequent patents are dependent on the original patent for gene A. Hence, the alleged legal certainty and lack of dependence and “opening up fields of research” arguments simply do not stand up to the “real life” biology of genomic nucleic acid molecules.

A further simple example examines the case where a gene encodes a protein A that has several different functions A1, A2, and A3 in a cell. A first patentee may find the first function A1 and obtain a patent for gene A for expressing protein A for function A1 in a cell. A second patentee may find the function A2 and obtain a patent for gene A for expressing protein A for function A2 in a cell. A third patentee may find the third function A3 and obtain a patent for gene A for expressing protein A for function A3 in a cell. As stated above, this sort of multiple function of a gene is not something theoretical – the biology of genetic information is inherently complex and intertwined. While all of these patents have claims that are purpose limited product claims, all of these patents would be dependent on each other because the patented gene will inevitably express protein A with all three functions and each of the three patentees can assert that the gene is performing the function according to its patent claim when expressed in a cell. It can be seen on hand of this example that limiting the original patent to a gene having a certain function does not serve to increase legal certainty or clear a field for parties other than the original patentee because the subsequent patents would all still be dependent on the original patent.

5) The purpose and transposition of the Directive.

Some parties believe that the mentioning of gene sequences as a specific matter of regulation in Directive 98/44, the attempt of the legislator to combine both the patentability and the scope of protection with the biological function of gene sequences, and the Resolutions of the European Parliament (as cited) from 2001 and 2005, are all in line with this interpretation.

However, the majority of the Experts are of the opinion that these arguments are not convincing.

While gene sequences are mentioned as a specific matter of regulation in Directive 98/44/EC, the attempt of the legislator was to codify a uniform and harmonising law with regard to biological

material that is capable of self-replication and being passed to a future generation of organisms (cell, plants, animal, etc.). In addition, while the Directive addresses both patentability issues and scope of protection issues, these two aspects of patent law must be considered separately and should not be intertwined in a manner that the CJEU did in its decision C-428/08. Moreover, the majority (11/15) of Experts are of the opinion that to combine both the patentability and the scope of protection issues with the biological function of gene sequences by requiring that the function of a given gene be required in the claims of a patent, and not just the description, is not intended by the Directive.

The majority of the (11/15) Experts do not see any reason whatsoever for introducing purpose-limited product protection for nucleic acid molecules. These Experts are of the conviction that the Biotechnology Directive was not implemented with the idea of providing a framework for such limitation. Rather, these Experts recognize the Directive as an instrument to encourage the development of the Biotechnology industry in the EU. Moreover, these Experts are convinced that the Directive was meant to provide protection for self-replicating biological material based on the explicit wording of Article 9 and do not see any indication of a purpose-limitation in the chapter in the Directive on patentability. In particular Article 3 and 5 of the Directive do not serve as a basis for such a concept.

6) Consequences for Past and Present Patent Filing and Patent Enforcement

The majority (11/15) of the Experts are of the opinion that, if past and present claims were to now be interpreted as being purpose-limited, the following non-limiting range of problems/complications can/will arise in the future:

- when interpreting the term “performs its function”, the “function” would have to be defined for each individual nucleic acid molecule, depending on the information provided in the patent application. Questions that beg to be answered in this regard are: which function; how general can the function be; what if there are several functions; etc.;

- the “function” would complicate interpretation of the claims in terms of infringement because, instead of simply comparing the sequence of a nucleic acid molecule with a potentially infringing sequence, a court would have to consider this functional language;

- changing the law *ex tunc* would disadvantage a patentee/applicant who filed an application prior to decision C-428/08 because the patentee/applicant did not have the opportunity to consider formulating the “function” that would be required for purpose-limitation at its broadest scope;

- limiting the claims to a specific function or limiting the scope of protection to situations where the nucleic acid performs its function could be seen by many branches of the commercial biotechnology research community as a discouragement because the “reward” for isolating a nucleic acid from nature and ascertaining its function is a time, labour and financially intensive would not be commensurate with the contribution of the invention to the public as it is in other fields of technology.

Annex C6. Minority view on introducing function-limited protection for DNA

1) Scope of protection versus contribution to the public. Absolute product protection for genomic nucleic acid molecules would overly reward the patentee with a scope of protection that is beyond the patentee's contribution to the public. Isolating a genomic DNA sequence or gene should not entitle patent holders to an exclusive right covering all uses of the patented DNA sequence because the nucleic acid sequence of a gene and its function is inherent in an organism, and the isolation and determination of the nucleic acid sequence of a gene is much more a discovery than an invention. It might indeed be the case that these discoveries are labour and time intensive and associated with a certain amount of risk, but this does not alter the fact that genomic DNA per se is something found in nature and as such cannot be an invention without knowing its function. This situation is also different for traditional chemistry, where an inventor creates a molecule that did not exist in nature. Therefore, the function must be included in the claim to limit the scope of protection to that which the patentee actually contributed to the public.

2) Special nature of genomic nucleic acids as carriers of genetic information. Genomic DNA is also different from other molecules because of its informational value. One reason for this lies in the function of DNA: While it is true that DNA can be described as a relatively simple biochemical polymer of individual nucleic acids, its biological function cannot be reduced to the characteristics of its chemical components. Much more genomic DNA has to be regarded as a code of information that reveals its function in a much more complex way. It is not the individual chemical substance that defines the biological function of the DNA, but the context in which the DNA is placed. Indeed, most of the functions of a genomic DNA molecule are dependent on its cellular environment: Many variants of a particular genomic DNA sequence can be found across the boundaries of the plant and animal kingdom, but their specific function within the cells of a given species might be different and depend on the biological context.

To describe the difference to the functions of other chemical substances the following comparison was made: Many chemical substances that for example can render pharmaceutical effects, show several functions. However in most cases, the number of these functions will be limited and specific. On the other hand, the functions of the chemical elements of the Periodic Table are not limited and not specific. Looking to the functionality of nucleic acids these should be considered as being much more in line with the elements of the Periodic Table, than with those more specific chemical compounds with a more specific activity. As a consequence, no absolute patent protection should be provided to nucleic acids nor to the elements of the Periodic Table, nor to any other component of biological or chemical substance which functions are not limited and not specific.

Finally, since the ratification the Directive, our knowledge about the complexity of gene function and gene regulation has greatly increased. Therefore there are even more reasons why absolute product protection should not be given.

3) Possibility to “work around” a patent claim on genomic DNA. One cannot “invent around” a patented genomic DNA sequence, i.e. invent a different DNA sequence that would have a better function, although this is often but not always possible for more traditional chemical molecules. The reason for this is that evolution has placed constraints on the structure of genes. In other words, only nucleic acids are capable of forming DNA and only the nucleic acids DNA or RNA are capable of

carrying genetic information to encode proteins – this cannot be done by some other chemical molecule. Hence, one is forced to use DNA/RNA if one wants to express a protein in a cell. Also, if one were to try to diagnose a disease, one would be forced to use a mutation that causes the disease and occurs in nature. This effectively forces parties other than the patentee to either obtain a license from the patentee or forego conducting further research on the patented genomic DNA.

4) Dependency of third parties on first patent to a given gene and encouragement/discouragement to research. Limiting the scope of protection for genomic DNA molecules would encourage research. By limiting claims to genomic DNA with a specific function, the patentee would only obtain protection for this function. This would have two major effects. On the one hand, this would prevent a patentee from blocking entire fields of research. This, in turn, would allow third parties to experiment in fields that are related to the originally patented function of a gene and encourage research and development in these related fields. On the other hand, since a subsequent patent would not be dependent on the first patent, the second patentee would not be commercially or economically restricted by the first patent. While this is a general argument with regard to scope of protection, it is particularly relevant to genomic DNA sequences because of their quality regarding information and functionality. Otherwise, this effectively forces parties other than the patentee to either obtain a license from the patentee or forego conducting research on the patented genomic DNA. For example, if a patentee has found a use of DNA for diagnosing a disease, a subsequent patent which discloses and claims a therapy for the disease using the DNA should not be dependent on the first patent.

5) Legal certainty for third parties. Limiting protection of a genomic DNA molecule to a given function would simplify the determination of whether a third party would infringe a patent claim to genomic DNA molecule with a particular function because each patent would be restricted to that function alone. Thus, third parties would know whether they were working within or outside the protective boundary of the patentee and this would provide them with legal certainty.

6) The purpose and transposition of the Directive. The mentioning of gene sequences as a specific matter of regulation in Directive 98/44, the attempt of the legislator to combine both the patentability and the scope of protection with the biological function of gene sequences, and the resolutions of the European Parliament as cited from the years 2001 and 2005, are all in line with this interpretation.

In the view of this, one of the Experts is of the opinion that the Commission should render a legal clarification to make sure that the decision of the CJEU and the national laws in France, Germany, Luxembourg and Italy as well as the resolutions of the EU Parliament are correct in the interpretation of Directive 98/44/EC and that other countries and the EPO should seek to bring their decision making in line with this interpretation. Furthermore, the Commission should also clarify that no absolute product protection can be given if inventions overlap with the exclusions of Article 4: If the scope of an inventions overlaps with what is excluded from patentability such as plant and animal varieties or usage of essentially biological processes for breeding (or the products derived), the scope of the patent has to be limited to avoid any overlap.

Annex C7

Dissenting Opinion on Expert Group Report on the Scope of Protection in Europe of Patent Claims Directed to Nucleic Acid-Related Inventions

Authored by Ingrid Schneider

The essence of this Opinion is supported by Christoph Then

This document is a dissenting opinion to the Expert Group Report on the Scope of Protection in Europe of Patent Claims Directed to Nucleic Acid-Related Inventions (hereinafter referred to as the “Report”) of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering (E02973).

Some members of the Expert Group could not consent to the *Report* and its opinion, even though these members share the Expert Group's unanimous view that the CJEU decision in *Monsanto v Cefetra* was right in rejecting Monsanto's complaint.

However, this dissenting opinion does not share the majority's view that only absolute protection for nucleic acids is in accordance with Directive 98/44/EC. In contrast, we argue that the CJEU in its *Monsanto* decision did effectively introduce purpose- or function-limited protection for DNA sequences.

Summary

The CJEU decision in *Monsanto C-428/08* has provided a general, authoritative, clarifying statement for the interpretation of Directive 98/44/EC which confirms that protection for DNA sequences is limited to the purpose or function of a novel DNA sequence which the inventor has discovered, plausibly, credibly, and sufficiently described in the patent application, and for which an industrial application was provided. Thus, the absolute product protection doctrine established for chemical substances has no validity for DNA sequences, and has been expressly rejected by the CJEU.

The reasons and rationales for both the CJEU's and the national legislator's abolishing of absolute product protection for gene sequences are based on important legal, scientific, fairness, public policy, science and innovation arguments.

By clarifying that "absolute protection to the patented product as such" is not possible, the CJEU provides for EU wide harmonisation of the protection for DNA sequences/ nucleic acids related inventions and prevents the law from being interpreted differently in the national jurisdictions. It thus ensures uniform and coherent application of Directive 98/44/EC. Moreover, it brings EU law in line with international legal developments, and hence is fostering international legal approximation.

Reasons and rationales for restrictions of patent scope for DNA

As stated in the *Report*, five countries - Germany, Italy, France, Luxembourg and Poland - in their national implementation of Directive 98/44/EC passed amendments in legal texts to specify and clarify the wording of said Directive. Despite of the differences in the way these amendments were phrased, they share a common purpose, namely the reduction of scope of DNA sequences and other nucleic acid-related inventions (See explanation in Annex).

The CJEU in its decision *Monsanto v. Cefetra*, C-428/08, answered Question 2 as follows:

"2. Article 9 of the Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes the national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it."

The CJEU decision in *Monsanto* C-428/08 has thus provided a general, authoritative, clarifying statement for the interpretation of Directive 98/44/EC which confirms that protection for DNA sequences is limited to the purpose or function of a novel DNA sequence which the inventor has discovered, plausibly, credibly, and sufficiently described in the patent application, and for which an industrial application was provided. Thus, the absolute product protection doctrine established for chemical substances has no validity for DNA sequences, and has been expressly rejected by the CJEU.

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In specifying and clarifying the scope of protection for gene sequences, DNA and other nucleic acid molecules as such, the Court also took into account scientific developments and insights which were gained after Directive 98/44/EC was passed in 1998. Some of this scientific knowledge which also prompted several national legislators to pass amendments in legal text shall shortly be mentioned and recapitulated.

Scientific developments and their impact

- The publication of the complete sequence of the human genome in 2001, and the complete sequencing of the genomes of many other organisms such as animals, plants, bacteria and viruses has effectively destroyed the novelty of claims directed to the nucleic acid molecules which form part of these genomes.
- The inventive step, therefore, can only consist in disclosing a specific function of the DNA sequence, and in providing an industrial application for this function. As more and more DNA sequences became known and characterised, it had also become possible, through bioinformatic homology searching and other tools, to guess about the function of a newly discovered DNA sequence. In order to prevent speculative assertions of functions in patent applications, the patentability requirements have to be applied strictly, and the inventive step cannot consist in just providing the structure of the DNA sequence.²⁰⁸
- The human genome sequencing consortium in 2001 also rectified previous assumptions about the numbers of genes in the human genome. While in the 1990s it was assumed that the human genome is comprised of 100,000 genes, in 2001 it was revealed that the human genome only contained 30 to 40,000 genes (hardly more than a thread worm who contains 20,000 genes), a number later even corrected downwards to 20 to 25,000 genes.²⁰⁹ Once more, this elucidated the fact that the regulation *between* different DNA sequences as well as between genes and the environment, inter alia via epigenetic factors, is decisive for the function of the gene in a complex pathway of an organism or for the role of a specific gene for a certain disease. Since then, a lot more evidence for the multi-functionality of DNA sequences has been gathered. Thus, it became evident that first, the 'cake' to be distributed was much smaller as previously assumed, and second, that granting all possible functions of a DNA sequence to the first inventor, as the absolute protection doctrine prescribes, would overly reward this inventor and deprive all other inventors from just reward.
- Moreover, there were other reasons why scientists argued that it should not be possible to obtain patent protection on all potential functions of biological material, such as a gene, and that patent protection should be restricted to specific functions. Among others, a major change in the scientific paradigm from a causal towards a systemic theoretical perspective on genes occurred. The old so-called "central dogma" in genetics ("One Gene, One Enzyme Hypothesis") was modified and largely replaced by a more complex model which states that one DNA sequence can code for many different proteins. There are several post-transcriptional mechanisms (such as RNA editing or alternative splicing) that allow for genes to potentially make multiple polypeptides. This enables the human genome which contains around 22,000 genes to produce somewhere between 500,000 to 1.5 million different proteins.
- Meanwhile, it became clear that the old, linear and causal model between genotype and phenotype was only valid for some monogenetic characteristics and a number of relatively

²⁰⁸ Straus, J. 2001b: Produktpatente auf DNA-Sequenzen - Eine aktuelle Herausforderung des Patentrechts, in: *GRUR* 10-11: 1016-1021, on p. 1019; Krefft, A.R. 2003: Patente auf human-genomische Erfindungen. Cologne.

²⁰⁹ International Human Genome Sequencing Consortium 2001: Initial sequencing and analysis of the human genome, in: *Nature*, vol. 409, 15.2.2001: 860-921 on 898-901; Pearson, Helen 2006: What is a gene? In: *Nature*, vol. 441: 398-401.

rare diseases. Hence, genes are no longer described as a certain sequence of the DNA but as *functional unit*, and thus in relational terms. Therefore, the old assumption that a gene can be characterised by merely giving the "letters" of its DNA sequence, had to be overturned.

Legal Implications

- This also implies that the subject matter of a patent application for a DNA sequence is not the DNA sequence as such, but the DNA sequence in combination with the function which it codes for, like for instance the production of a certain protein or the coding for a certain disease. Hence, the subject matter of the patent is the functional unit, that is the DNA sequence tied to the function. This in turn means that the scope of protection is also affected, because the claims can only claim the scope of the functional unit, not all other functions which were not revealed and are often not even known to the inventor. Therefore, in this case, the patentability issue is inextricably linked with the scope of protection.
- Furthermore, it has been rejected to simply equate DNA sequences or genes with chemical compounds. Even though it is true that DNA is a biochemical substance (nucleic acid), the essence of what makes genes special is that DNA encodes information, and hence DNA is a carrier of information from which different products, such as proteins, emerge. Thus, it has been argued, that »the fact that genes are essentially just genetic information makes the issue of patenting them very different from that involved in the isolation of other chemical compounds«²¹⁰. Moreover, the nucleic acid as substance is less important than its informational component. It is also important to emphasise that the inventive step for a DNA sequence does not consist in the mere isolation of the sequence but in the characterisation of its function.

Fairness, Innovation, and Public Policy

- Apart from these scientific facts and their legal implications, the restriction of scope to the function of a DNA sequence has also been defended by arguments which are related to fairness and to an anticipatory impact assessment of the public policy and innovation consequences of DNA patents too broad. The fairness argument says that granting the first inventor all possible functions of a DNA sequence would overly reward the inventor, and would not do justice to other inventors who may invest the same or even more efforts, time and financial investments in revealing another function of the same DNA sequence.
- While granting patents on diagnostic and therapeutic inventions based on DNA sequences may result in a great benefit to society, it also presents a multitude of risks,
 - that overly broad patent rights will stifle and jeopardize scientific progress;
 - that it will restrict access in ways that discourage "follow-on" innovation;
 - that it will lead to industry concentration in a way that hurts patients, consumers or citizens, for instance by raising the prices for diagnostic tests, biomarkers and drugs.

²¹⁰ Nuffield Council on Bioethics (NBC) 2002: *The ethics of Patenting DNA*. U.K., p. 28.

- Scientists have been concerned that patents granted too much upstream in the research process could be detrimental to academic freedom.
- Moreover, economists argued that too early and too broad patent protection carries the risk that the temporary monopoly is unnecessary to produce the innovation, or that it is broader or lasts for longer than is necessary to encourage future scientific progress. Therefore, it is necessary to strike the right balance between patentability issues, scope of protection, and the public domain.
- This list of risks could be continued. Therefore all patent laws contain clauses and rule with exceptions, limitations, and restraints designed to prevent such risks. The restriction of patent scope forms such a preventive element.
- While patent law is guided by the assumption that patents foster innovation and diffusion of knowledge, it must be taken into consideration that patents can also impede scientific progress. Much debate and scientific literature has been devoted to patents on "research tools" and to "reach through claims" which can create broad dependencies and may block research and development. "Patent thickets" may be the result of a multitude of overlapping patent rights which in turn can increase transaction costs or lead to royalty stacking which may make the industrial application of an invention prohibitive.

Conclusions by national legislators

Taken all these considerations together, the five national legislators (Germany, Italy, France, Luxembourg, Poland) have taken a wise and appropriate decision to explicitly restrict the scope of DNA patents to the function or purpose of the respective DNA sequence as disclosed and revealed, and thus to avoid too many dependencies for additional and follow-up inventors.²¹¹ These measures are not only legally covered by Directive 98/44/EC, in particular its Article 5(3), but also by the general fact that patent protection is based on a social contract, and that it would be contrary to the *quid pro quo* forming the foundation of the patent system to tip up this balance, and to overly reward the inventor.

The fact that not all national legislators amended the wording of the Directive does not mean that they opposed the solutions enshrined in the laws of some Member States. On the contrary, it must

²¹¹ These legislative processes were based on expert reports and intense deliberations in national parliaments. For *France*, see CCNE (Comité Consultatif National d’Ethique) 2000: *Avis sur l’avant-projet de loi portant transposition, dans le code de la propriété intellectuelle de la directive 98/44/CE du Parlement européen et du Conseil, en date du 6 juillet 1998, relative à la protection juridique des inventions biotechnologiques*. N°64 – 8 Juin 2000, and the letter by *President Jacques Chirac* to the President of the European Commission from 30 June 2000. For the *German* debate see in particular the highly influential statement of the Parliamentary Study Commission on Law and Ethics in modern Medicine (*Zwischenbericht der Enquete-Kommission »Recht und Ethik der modernen Medizin«*. Teilbericht zum Schutz des geistigen Eigentums in der Biotechnologie». BT-Drs. 14/5157, 25 January 2001). For the long parliamentary debates, expert hearings and the very intense debate in the patent law community with over 50 scientific articles in legal journals see Schneider, I. 2010: *The European Patent System. Shifts in Governance through Parliaments and Civil Society* (Das Europäische Patentsystem. Wandel von Governance durch Parlamente und Zivilgesellschaft), Frankfurt/New York. See also the subsequent prevailing opinion in the German legal patent literature which supported and confirmed functional restriction of patent scope for DNA (Kraßer, R. 2004: *Patentrecht*. Munich, (5th Edition), p. 233.

be emphasised that discussions and challenges to gene patents and to absolute protection in scope for DNA have taken place in many more EU members states. Just to mention the *UK*, where the Royal Society and the Nuffield Council warned against adverse effects to science.²¹² In *Denmark*, the Ethics Council²¹³ after broad public discussion issued two critical reports. In the *Netherlands*, critical voices were raised in an interdepartmental working group²¹⁴, and in *Sweden* several research councils critically debated absolute product protection for DNA.²¹⁵

Some EU member states decided for other legislative measures to address the concerns and problematic issues of unbalanced patent protection, especially for genes. Belgium, for instance, introduced a compulsory licence for purposes of public health, and extended the scope of the research exemption by allowing it not only for research 'on' but also for research 'with' the patented product or process, an exemption which also covers research tools.²¹⁶ The same broad exemption is valid in Italy, and the Netherlands exempts academia in a wider sense from patent infringement.²¹⁷ Austria also discussed the concerns about gene patents and introduced a patent ethics committee to regularly monitor respective national patents and to report to both Government and Parliament.²¹⁸

As mentioned in the *Report*, the European Parliament issued two resolutions which also raised concerns about adverse effects of DNA patents, and respectively called for purpose-bound protection.²¹⁹

Conclusion by the CJEU and legal implications

We assume that the Court of Justice of the EU was aware of these aforementioned scientific insights, arguments and debates, and therefore took question 2 of the Monsanto case as an opportunity for clarification and EU wide harmonisation. Such judicial activism by the CJEU, even though at times criticised, is not uncommon but rather the rule in the EU.

²¹² Nuffield Council on Bioethics 2002: *The ethics of Patenting DNA*. U.K.; Royal Society 2003: *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science*. London.

²¹³ DCE (The Danish Council of Ethics) 1994: *Patenting human genes: A Report*. Copenhagen. DCE (The Danish Council of Ethics) 2004: *Patenting human genes and stem cells*. Copenhagen.

²¹⁴ Interdepartementale Werkgroep 2005: *Ethische aspecten aan octrooiverlening voor biotechnologische uitvindingen*, Amsterdam, NL, 23-6-2005.

²¹⁵ SNCME 2002: The Swedish National Council on Medical Ethics: *Opinion* on Directive 98/44/EC on the legal protection of its biotechnical inventions, and its implementation in Sweden, Stockholm, 25.02.2002; SOU 2006: Oinskränkt produktskydd för patent på genteknikområdet. Delbetänkande av Kommittén om patentskydd för biotekniska uppfinningar.

²¹⁶ *Loi Belge* du 28 avril 2005. – Loi modifiant la loi du 28 mars 1984 sur les brevets d'invention en ce qui concerne la brevetabilité des inventions biotechnologiques.

²¹⁷ See: Kupecz, András et al. 2015: Safe harbors in Europe: an update on the research and Bolar exemptions to patent infringement, in: *Nature Biotechnology* 33: 710–715, see Table 1 for other EU countries; http://www.nature.com/nbt/journal/v33/n7/fig_tab/nbt.3273_T1.html.

²¹⁸ Beschluss der Bioethikkommission beim Bundeskanzleramt vom 6. März 2002. *Stellungnahme der Bioethikkommission zur Frage der innerstaatlichen Umsetzung der Biotechnologie-Richtlinie*. Wien, Österreich.

²¹⁹ European Parliament 2005: *Resolution on patents for biotechnological inventions*, Point 5, www.europarl.europa.eu/sides/getDoc.do?sessionId=3CEC3F2B9A6DB6F08C3C22BFF958CBFE.node2?pubRef=-//EP//TEXT+TA+P6-TA-2005-0407+0+DOC+XML+V0//EN

Even though some observers complained about the way the CJEU has phrased its decision in the Monsanto case, and many had wished for a more extended and precise guidance, there is no doubt that the CJEU judgement is a turndown for absolute product protection for DNA sequences.²²⁰

The CJEU rightly based its decision mainly on Article 9 of Directive 98/44/EC, because this is the article related to patent scope. However, for a correct interpretation and application of the decision, Article 9 must be read in combination with Article 5.

The fact that the CJEU's Monsanto decision was not often cited in national patent law cases does not render it irrelevant or incorrect. In contrast, the rule of law, respect for the separation of powers in the EU, and for the EU's Court of Justice as important institution of the union, calls for adherence of its judgement.

We therefore regret that the majority of Experts could not be convinced to take up affirmative interpretations and supportive rationales to the Monsanto ruling and, more generally, to the restriction of patent scope for gene sequences.

If we approach this case from an international perspective, this opens up a broader horizon as we can see that similar debates and concerns were raised internationally. The U.S. Supreme Court, in the BRCA gene Case 'Association for Molecular Pathology v. Myriad Genetic' stated that „merely isolating genes that are found in nature does not make them patentable“.²²¹ This decision and other U.S. Supreme Court case law have sought to countervail overly extensive patent protection. Australia has a long tradition in broad expert and parliamentary debates on gene patents²²² as well, and in 2015 the High Court of Australia unanimously held that the claims to isolated BRCA1 genetic materials are invalid under Australian patent law, thus also abolishing patents for merely isolated genes which as such are considered natural products and non-eligible for patents.²²³

In conclusion, a functional restriction of the absolute scope of DNA patents is far from being noncompliant with the Directive 98/44/EC but on the contrary, it is an affirmation of the spirit and letter of the EU's Biotech Directive. Thus, the CJEU's Monsanto ruling is not only an important step in harmonising respective EU law but also brings EU law in line with international legal developments, and hence is fostering international legal approximation.

28 April 2016

²²⁰ Cf. Lamping, M 2010: Case Notes. Purpose-bound patent protection for genes, *EJRR* 4, 445-450.

²²¹ Association for Molecular Pathology v. Myriad Genetic, Inc., 133 S.Ct. 2107 (2013).

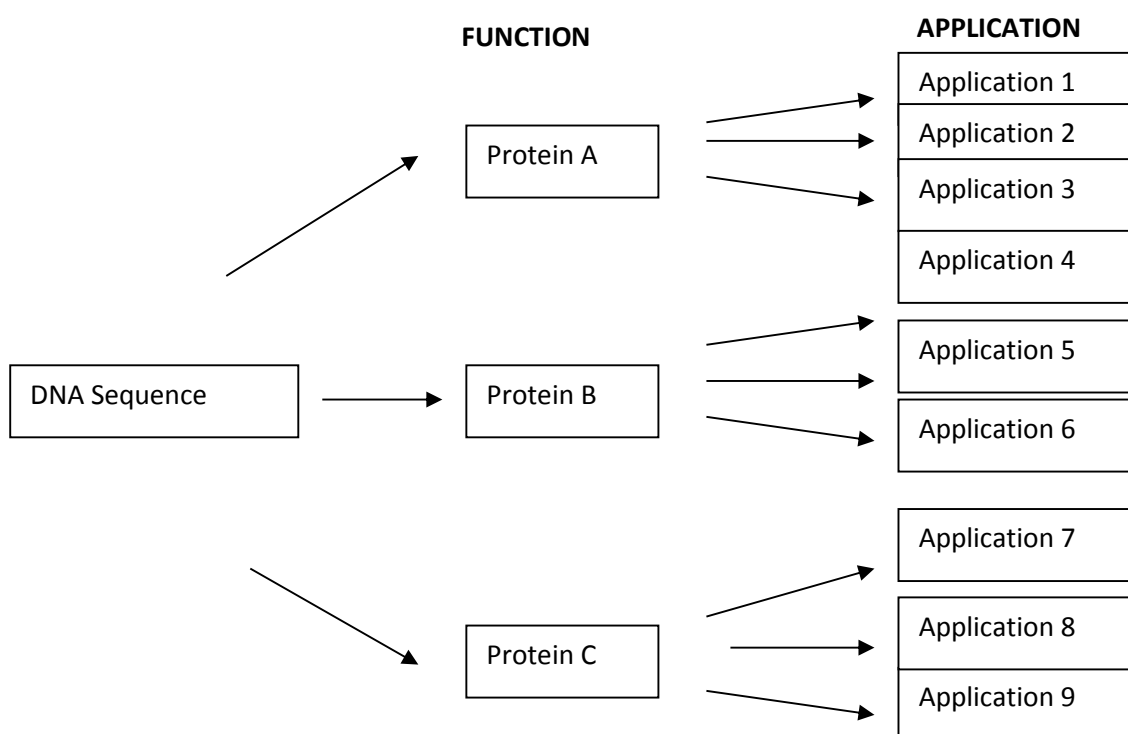
²²² ALRC (Australian Law Reform Commission) 2004: *Gene Patenting and Human Health*, (ALRC 68), Australian Government, Sydney; ALRC (Australian Law Reform Commission) 2004: *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99). Australian Government, Sydney.

²²³ *D'Arcy v Myriad Genetics Inc*, [2015] HCA 35, 7 October 2015, S28/2015.

ANNEX to dissenting opinion

The old 'composition of matter' patent doctrine for chemical substances which was applied by analogy to gene sequences, entails patent protection for all other functions and industrial uses of a particular DNA sequence if just one function (e.g., a protein produced) and one industrial application (e.g., a genetic test or gene therapy) is disclosed, even if the patentee has no knowledge about these other functions and applications. In contrast, function-bound protection ties the DNA sequence as functional unit to the function (protein or disease) disclosed in the patent application (= patent eligibility) and therefore restricts the scope of the patent to the industrial applications of this functional unit.

Graph 1: Absolute and function-bound protection for protein-encoding DNA



© Christine Godt

Absolute product protection:

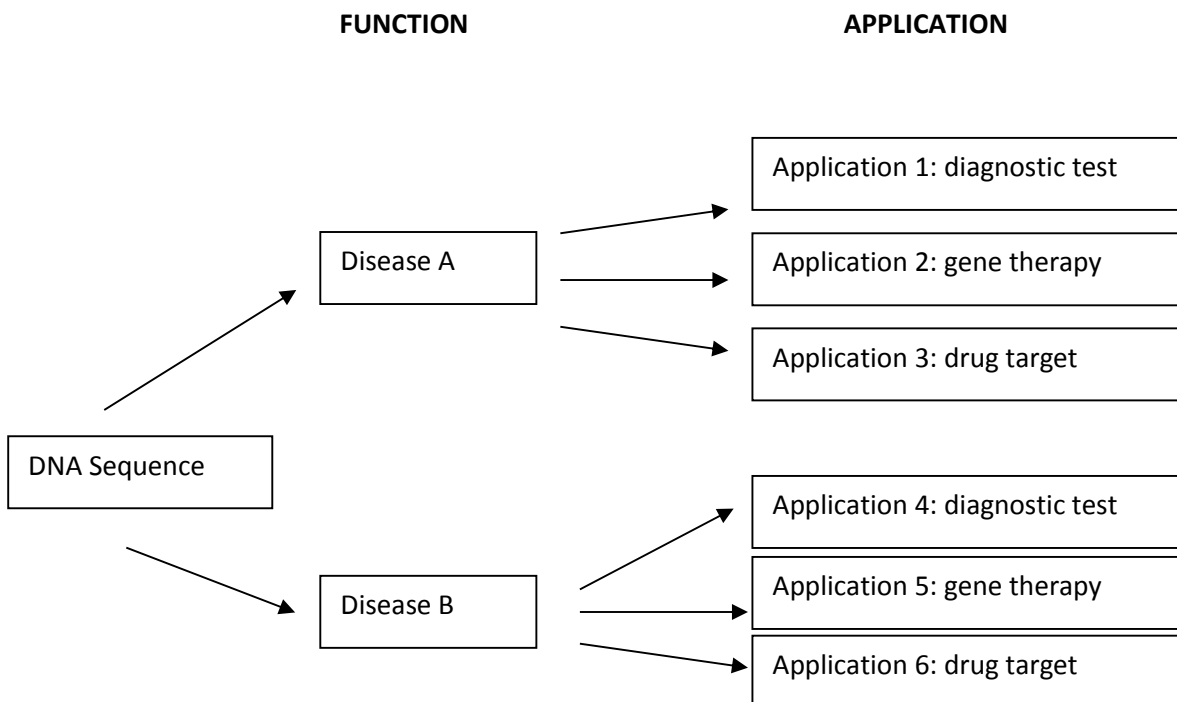
Disclosure of a DNA sequence and one single function (DNA + protein A) grants patent protection for all other functions (protein B, C, ...) of this sequence as well as all the applications for it (Applications 1-9, in principle endless)

Function-bound product protection:

Disclosure of the DNA sequence as functional unit with a function (DNA + protein A) grants patent protection for all the applications (1 to 3) related to this DNA sequence + protein A.

An inventor disclosing the DNA sequence as functional unit with another function (DNA + protein B) can receive a non-dependent patent and claim all the subsequent applications (4 to 6).

Graph 2: Absolute and function-bound protection for DNA and disease



© Ingrid Schneider

Absolute product protection:

Disclosure of a DNA sequence and a single disease (DNA + disease A) grants patent protection for all other functions (disease B, C, ...) of this DNA sequence as well as all the possible applications for it (Applications 1-9, in principle endless).

Function-bound product protection:

Disclosure of the DNA sequence as functional unit with a disease (DNA + disease A) grants patent protection for all the applications (1-3, ...) related to this DNA sequence +disease A.

An inventor disclosing the DNA sequence as functional unit with another function (DNA + disease B) can receive a non-dependent patent and claims to all the subsequent applications (applications 4 to 6, ...).